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No. _____

IN THE

Supreme Court of the United States

OCTOBER TERM, 1980

ALCON LABORATORIES (PUERTO RICO), INC., EDGAR H. SCHOLLMAIER, and JOHN W. FEIK, *Petitioners*

v.

UNITED STATES OF AMERICA, *Respondent*

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

THOMAS O. HENTELEFF
GLENN E. DAVIS
KLEINFELD, KAPLAN & BECKER
1140 Nineteenth Street, N.W.
Washington, D.C. 20036
(202) 223-5120

Counsel For Petitioners

Of Counsel:

MANUEL A. GUZMAN
McCONNELL VALDES KELLEY
SIFRE GRIGGS & RUIZ-SURIA
G.P.O. Box 4225
San Juan, Puerto Rico 00936

PETER R. MATHERS
KLEINFELD, KAPLAN & BECKER
1140 Nineteenth Street, N.W.
Washington, D.C. 20036

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QUESTIONS PRESENTED

1. Whether a District Court has authority in a "new drug" enforcement action arising under the Federal Food, Drug, and Cosmetic Act to remand the case before it to the primary jurisdiction of the Food and Drug Administration for a formal administrative determination of the "new drug" status of the drug at issue.

2. Whether in a "new drug" enforcement action arising under the Federal Food, Drug, and Cosmetic Act a District Court has authority to direct the Food and Drug Administration to defer further enforcement action pending a remand of the "new drug" issues to the Food and Drug Administration.

3. Whether a remand order in an enforcement action under the Federal Food, Drug, and Cosmetic Act constitutes an order in abatement within the meaning of 28 U.S.C. §2105 so as to preclude review or reversal of it by a Court of Appeals.

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v.

UNITED STATES OF AMERICA, *Respondent*

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

Alcon Laboratories (Puerto Rico), Inc., Edgar H. Schollmaier, and John W. Feik petition for a writ of certiorari to review the opinion and judgment of the United States Court of Appeals for the First Circuit.

OPINIONS BELOW

The opinion (App. A, *infra,* 1a-23a) and judgment (App. B, *infra,* 24a) of the United States Court of Appeals for the First Circuit are unreported. The February 27, 1980 remand Order of the United States District Court for the District of Puerto Rico (App. C, *infra,* 25a-26a) is unreported. The April 9, 1980 Opinion and Order of the District Court (App. D, *infra,* 27a-33a) is

[1] Pursuant to Rule 28.1 of the Rules of this Court, the parent companies, non-wholly owned subsidiaries, and affiliates of Alcon Laboratories (Puerto Rico), Inc. are Alcon Laboratories, Inc. and Nestle S.A.

unreported. The April 29, 1980 Order of the District Court (App. E, *infra,* 34a-36a) clarifying the District Court's two previous orders is unreported.

JURISDICTION

The opinion of the Court of Appeals vacating the Orders of the District Court was rendered February 24, 1981. The jurisdiction of this Court is invoked under 28 U.S.C. §1254(1).

STATUTORY PROVISIONS INVOLVED

The pertinent provisions of the Federal Food, Drug, and Cosmetic Act (hereinafter "FFDCA") are set forth in Appendix F, *infra,* 37a-42a.

STATEMENT OF THE CASE

This case concerns the regulatory status of the prescription drug WANS, an antiemetic (antivomiting) drug marketed by the petitioner, Alcon Laboratories (Puerto Rico), Inc.[2] Two of the three underlying consolidated actions are drug seizure actions under the FFDCA. These actions were filed in the District Court by the Federal Food and Drug Administration ("FDA") on September 21, 1978 and January 28, 1980, respectively, with the FDA invoking 21 U.S.C. §334 (the "seizure" provisions of the FFDCA, App. F, *infra,* 37a-38a) for jurisdiction. The third action, filed with the District Court on November 28, 1978, is an action in which the FDA seeks to enjoin Alcon from introducing WANS into interstate commerce without first obtaining

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[2] The other petitioners, Edgar H. Schollmaier and John W. Feik, are employees of Alcon Laboratories (Puerto Rico), Inc. The petitioners will be referred to collectively as "Alcon."

an approved new drug application ("NDA") for WANS. Jurisdiction in this action was invoked under 21 U.S.C. §332 (the injunction provisions of the FFDCA, App. F, *infra,* 38a-39a). All of these actions are based upon FDA's allegation that WANS is an unapproved "new drug"[3] and as such cannot be marketed in interstate commerce without violating the "new drug" provisions (21 U.S.C. §355, App. F, *infra,* 40a) of the FFDCA. In each of these actions, Alcon has denied that WANS is a "new drug" and has affirmatively asserted that WANS is entitled to "grandfather" protection (App. F, *infra,* 39a-41a), and that the enforcement actions against WANS based upon its alleged "new drug" status violate the FDA's Compliance Policy Guide 7132c.08 ("CPG"). The CPG is an advisory opinion/guideline which is made binding upon the FDA by its own regulations. *See* 21 CFR §§10.85 and 10.90.

Each of the WANS preparations (WANS No. 1, WANS No. 2, and WANS Children) is in a suppository dosage form and each contains as its active ingredients pyrilamine maleate and pentobarbital sodium. These ingredients are widely used by the medical profession in treating various disease conditions. The WANS preparations were first marketed in 1955 and since then have been continuously available to the medical profession as prescription drugs for use in the symptomatic treatment of uncontrolled vomiting.

Prior to WANS' introduction in 1955, it was determined that it was not a "new drug" as that term was then defined under the 1938 Act (i.e., it was generally recognized as safe). Based upon this determination, Alcon's predecessor in interest in WANS did not file an

[3] A "new drug" is defined in 21 U.S.C. §321(p) (App. F., *infra,* 39a-41a).

NDA, but rather marketed WANS as an "old drug." Several other companies reached a similar conclusion and marketed antiemetic preparations similar to WANS as "old drugs." WANS was marketed by Alcon from 1955 to 1978 with no questions being raised by FDA concerning the need for pre-market approval by the agency.

On March 17, 1978, 23 years after the product was first introduced into interstate commerce, FDA sent a Regulatory Letter to Alcon alleging for the first time that WANS is a "new drug" and requesting that Alcon discontinue marketing its product until it had obtained an approval from FDA. The Regulatory Letter also raised and attempted to deal with a formidable obstacle to regulatory action, the CPG. The Regulatory Letter stated:

> Please note that as listed in the CPG, your product(s) would fall under Part B "DESI and other Prescription Drugs where a final determination has not been made." *Ordinarily, drugs subject to this part of the CPG are not scheduled to be covered under a class action until a later time. However,* as further explained in the above-mentioned document, *it is Agency policy to initiate regulatory action against a violative product outside the established priorities* when such product becomes violative under another provision of the Act, or *if we receive significant new information which questions the safety and efficacy of the drug.* (Please see Policy Guideline Exceptions #2, Page 5). *Consequently because of new information concerning the safety and efficacy of these drugs, we are initiating regulatory action at this time.*

(emphasis added.) The sole ground for proceeding at this time against the class of drugs encompassing WANS was stated to be "new information concerning the safety and

efficacy of these drugs. . .'' i.e., the ''significant new information'' exception to the regulatory priorities established in the CPG.

In FDA's Regulatory Letter, the ''significant new information'' was said to consist of alleged reports of ''severe and sometimes fatal reactions'' with drugs containing pyrilamine maleate and pentobarbital, and the purported ''conclusion'' of the FDA's Neurological Drugs Advisory Committee that there is no evidence of the safety or efficacy of drugs containing pyrilamine maleate with or without a barbiturate in the treatment of nausea and vomiting.

Following the issuance of the Regulatory Letter, Alcon took several actions. It unsuccessfully attempted to ascertain the basis for this belated attempt by the agency to subject WANS to ''new drug'' status, including the basis for its allegation of the existence of ''significant new information.'' It provided the agency with data and information supporting the ''old drug'' status of WANS. It arranged for a meeting with FDA, during which it pointed out certain inaccuracies and distortions in the factual allegations contained in the Regulatory Letter, including the fact that neither the transcripts of the Advisory Committee meetings nor the underlying drug experience reports supported the allegation of ''fatal reactions.'' It is significant that at the meeting FDA was unable to provide any explanation as to the basis for the ''fatal reactions'' allegation except for a flippant statement by an FDA official that the reference was ''boilerplate.'' Following the meeting and in light of certain general concerns expressed during the Advisory Committee meetings as to the use of antiemetic therapy in certain children, Alcon notified the agency that it was revising its labeling for WANS to include additional precautionary information.

The FDA agreed to have its medical officer review these data and information, as well as the revised labeling, prior to irrevocably committing the agency to instituting regulatory action. However, without providing Alcon an opportunity to challenge administratively the agency's findings or conclusions, the agency summarily rejected the information submitted by Alcon and reiterated in a letter dated August 4, 1978 that in the absence of "voluntary market withdrawal" it was prepared to institute enforcement action.

Despite its inability to document or substantiate the existence of any "significant new information" and therefore in contravention of its own CPG, FDA instituted a massive, *ex parte* seizure of WANS on September 21, 1978, alleging that WANS is a "new drug." On the basis of its position that WANS is not an unsafe drug or a "new drug" and that enforcement action was improper under the CPG, Alcon continued to manufacture and market the drug subsequent to the seizure. This resulted in FDA's bringing a second action against WANS on November 28, 1978 in which it sought to enjoin further shipments of WANS in interstate commerce. FDA sought a temporary restraining order, but by Order dated November 29, 1978, the TRO was denied by the District Court. The two pending cases were also consolidated by this Order.

Alcon thereafter conducted extensive discovery of the FDA and its witnesses,[4] thereby establishing the absence of "significant new information" within the meaning of the CPG. Indeed, discovery established that

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[4] These witnesses were the same individuals whose statements FDA initially relied upon as the basis for its allegation of untoward effects.

the information cited in the Regulatory Letter was inaccurate and distorted as it related to the Neurological Drugs Advisory Committee's recommendations and was misleading insofar as it indicated any causal relationship between the administration of pyrilamine/barbiturate combination drugs and the purported untoward effects.[5]

In light of these discoveries, Alcon requested on March 21, 1979 that the District Court remand the pending actions to the primary jurisdiction of FDA for a determination of the "new drug" status of WANS. The Motion to Remand was premised in part upon the absence of any "significant new information" which would require a judicial decision of the "new drug" issues without the benefit of a formal administrative record or which would justify initiating enforcement action against WANS in contravention of the CPG. The Motion to Remand requested the District Court, in the exercise of its sound discretion and in recognition of the 25 year safe marketing history of WANS and the complex scientific issues involved, to "stay its hand" and remand the actions to the primary jurisdiction of FDA. *See CIBA Corp.* v. *Weinberger,* 412 U.S. 640, 644 (1973).

While the Motion to Remand was pending, the FDA, with no additional information (let alone the requisite "significant new information"), instituted a second massive, *ex parte* seizure action against WANS on January 28, 1980. On February 27, 1980, the District

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[5] Discovery established that each of these purported untoward effects could scientifically and reasonably be explained by independent factors such as excessive doses, dehydration, natural progression of the disease state, and concurrent medication. The District Court so held in its Order of April 29, 1980 (App. E, *infra,* 34a-36a).

Court, after reviewing the extensive documents before it (including the depositions of FDA's expert witnesses and the Advisory Committee transcripts), issued in the exercise of its sound discretion an Order which

> (1) consolidated the January 28, 1980 seizure action with the prior consolidated seizure and injunction actions;
>
> (2) granted Alcon's motion of March 21, 1979 and remanded the actions to the FDA with instructions to hold, in conformity with the CPG, a hearing pursuant to 5 U.S.C. §554 on the issue of whether WANS is a "new drug";
>
> (3) instructed FDA to defer regulatory action against the WANS preparations, or against the named defendants, based upon a "new drug" charge until FDA holds the administrative hearing referred to in paragraph (2) and makes an administrative determination of the "new drug" status of WANS;
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> (4) held the two seizures to be without effect; and, significantly
>
> (5) specifically retained jurisdiction over whether new, verifiable, and genuinely significant information comes to light which would justify enforcement action against WANS out of the sequence provided in the CPG.

App. C, *infra,* 25a-26a. On April 9, 1980 the District Court issued its formal Opinion and Order (App. D, *infra,* 27a-33a) and on April 29, 1980 it denied the FDA's request for a stay pending appeal (App. E, *infra,* 34a-36a). In the last Order, the District Court reiterated that it was retaining jurisdiction over the entire matter by ordering that one box each of WANS No. 1, WANS No. 2, and WANS Children from each of the seizures be retained under seal pending a final determination of the "new drug" status of WANS.

The FDA filed separate appeals from the Orders of February 27 and April 9, 1980. Alcon sought summary dismissal of the appeals, asserting that the remand Orders were non-final and therefore not appealable under 28 U.S.C. §1291, and in the alternative that the Orders merely abated the actions and therefore were non-appealable under 28 U.S.C. §2105.

On June 23, 1980, the Court of Appeals issued an order deferring action on Alcon's motions for summary dismissal until consideration of the merits. On the same date, the Court of Appeals granted the FDA a stay pending appeal with respect to the District Court's order "enjoining" future seizures and ordering the return of quantities of the drug already seized.

On October 6, 1980, four days before oral argument in the Court of Appeals and over three months after the District Court's order deferring regulatory action had been stayed, the FDA instituted a third, massive *ex parte* seizure of WANS. Alcon moved immediately to dismiss this third seizure action on the ground that it violated the "multiple seizure" provisions of the FFDCA. As an alternate ground for dismissal, Alcon argued that under the circumstances of the ongoing litigation, the failure to obtain judicial scrutiny prior to the seizure was an unconstitutional denial of due process of law. Citing the Court of Appeals' opinions as making judicial scrutiny meaningless, the District Court denied the motion to dismiss in an Order entered March 18, 1981. *United States* v. *Articles of Drug . . . WANS*, No. 80-2112 (D.P.R. Mar. 18, 1961).[6] Although this Order is not

[6] According to Judge Perez-Gimenez, judicial scrutiny would result in a meaningless exercise for the Court. The Court would not have jurisdiction to prohibit the institution of seizure under the Act even if the Court in a pre-seizure "review" were to find that the action might involve an abuse of discretion or was not supported by the statute. A court properly should decline to reach such an illogical result.

presently before this Court, the Order emphasizes the importance of this Court's review of the issues presented by this petition.

On the merits of FDA's appeal, the Court of Appeals rejected all of Alcon's arguments and vacated the District Court's Orders. Its opinion of February 24, 1981 held, *inter alia:*

> (1) that the District Court's direction to FDA to defer regulatory action constituted an injunction appealable under 28 U.S.C. §1292(a)(1) and that enjoining regulatory action under the FFDCA violates this Court's ruling in *Ewing* v. *Mytinger & Casselberry, Inc.,* 339 U.S. 594 (1950) (App. A, *infra,* 7a-9a);
>
> (2) that the District Court's dissolution of the two seizures was appealable as a "collateral order" (*Cohen* v. *Beneficial Industrial Loan Corp.,* 337 U.S. 541 (1949)) and that the District Court lacked authority to dissolve the seizures prior to consideration of the merits of the seizure proceedings (App. A, *infra,* 10a-12a);
>
> (3) that the Order remanding to the primary jurisdiction of the FDA was an appealable "collateral order" and that the District Court exceeded its authority by issuing such an order in this enforcement proceeding under the FFDCA (App. A, *infra,* 12a-23a);
>
> (4) that it would decline to apply 21 U.S.C. §2105 (which precludes federal appellate review of orders in abatement) to preclude its jurisdiction because, the Court reasoned, Section 2105 is little used and "has never been interpreted as a significant limitation on federal appellate jurisdiction. . ." (App. A, *infra,* 15a n.2).

REASONS FOR GRANTING THE PETITION

1. The Decision Below Conflicts With The Decisions Of This Court Which State That A Court Can Remand The "New Drug" Issues In An Enforcement Proceeding To The Primary Jurisdiction Of The Food And Drug Administration

The Court of Appeals ruled that in the context of a "new drug" enforcement proceeding the District Court's Orders remanding the issue of WANS' "new drug" status to FDA's primary jurisdiction were in error. App. A, *infra,* 12a-23a. Citing its own decision in *ICC* v. *B & T Transportation Co.,*[7] 613 F.2d 1182, 1187 (1st Cir. 1980), the Court of Appeals held that such a remand "makes little sense" in an enforcement proceeding where the enforcing agency's views are already known. This holding ignores the fact that FDA's views were constantly shifting,[8] as well as the findings of the District Court that FDA's enforcement activities were predicated upon "contradictory" and "insufficient" information (App. E, *infra,* 35a n.1).

Apparently in deference to this Court's decisions in *CIBA* and *Weinberger* v. *Bentex Pharmaceuticals, Inc.,*

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[7] The *B & T Transportation* case involved issues concerning the Interstate Commerce Commission, not the FDA. In *B & T,* the Court of Appeals (in dictum) indicated that a remand in an ICC enforcement proceeding would be futile, explaining that a remand would be inappropriate because the issues to be remanded did not fall within the primary jurisdiction of the ICC. 613 F.2d at 1187 n.8. That is clearly distinguishable from the situation here where, as this Court has held, the "new drug" issues are within the FDA's primary jurisdiction.

[8] Thus, for example, FDA abandoned its reliance upon the CPG and the "significant new information" exception to the CPG when discovery made it clear that under the CPG the pending enforcement actions against WANS could not be justified.

412 U.S. 645 (1973), the Court of Appeals attempted to draw a distinction between remands affecting only one drug and one company, which it considered inappropriate, and remands with potentially broader effect involving drugs manufactured by many different companies. App. A, *infra*, 22a. Not only does this distinction lack legal justification but, as applied to the facts of this case, does not support the Court's ruling. WANS is but one representative of a *class* of combination antihistamine/barbiturate antiemetics whose status as "new drugs" is questioned by this proceeding. Indeed, the Regulatory Letter described the action against WANS as a "class action" involving all antihistamine/barbiturate antiemetics and was but one of a number sent in 1978 to the manufacturers of such drugs. These facts are corroborated by an FDA affidavit (which was before the Court of Appeals) in which an FDA compliance officer cites as reasons for expediting the trial in the District Court the agency's fears that three firms were about to resume marketing of WANS-type preparations. In any event, the distinction between remands involving one drug and a class of drugs is a spurious one which has no precedent other than the one here under review.

More importantly, the Court's ruling misinterprets and clearly conflicts with the principles announced by this Court in several "new drug" cases. In *CIBA Corp.* v. *Weinberger,* 412 U.S. 640, 644 (1973), this Court stated:

> Cases may arise where there has been no formal administrative determination of the "new drug" issue, it being first tendered to a district court. Even then, however, the district court might well stay its hand, awaiting an appropriate administrative determination of the threshold question.

On the precise issue of whether a remand is proper in an enforcement proceeding, this Court spoke with equal clarity in a companion case to *CIBA:*

> Even where no such administrative determination has been made and the issue arises in a district court *in enforcement proceedings,* it would be commonplace for the court to await an appropriate administrative declaration before it acted.

Weinberger v. *Bentex Pharmaceuticals, Inc.,* 412 U.S. 645, 652 (1973) (emphasis added).

The rejection by the Court of Appeals of this Court's endorsement of remanding "new drug" issues to FDA's primary jurisdiction also conflicts with the opinions of several other courts. In *IMS Ltd.* v. *Califano,* 453 F. Supp. 157 (C.D. Cal. 1977), the drug manufacturer had received a Regulatory Letter (analogous to the one here) alleging that its drug was a "new drug" and threatening enforcement action. The manufacturer sued for a declaratory judgment to the contrary.[9] The Court reviewed Supreme Court case law on FDA's primary jurisdiction and the appropriate circumstances in which to invoke such jurisdiction, and dismissed the action on

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[9] In *IMS,* the FDA had announced in its Regulatory Letter that in the absence of "voluntary" market withdrawal of the drug at issue it was prepared to utilize its enforcement powers, including seizure and injunction actions. Based upon this threat of immediate enforcement action, IMS sought declaratory relief in federal district court. To distinguish *IMS* on the ground that it involved a declaratory action rather than an enforcement action would be to draw a spurious distinction in favor of the drug company which seeks declaratory relief rather than the company which tries, although unsuccessfully, to convince the agency of the inappropriateness of the enforcement action.

the ground that the "new drug" issue should first be resolved in an administrative setting. The Court stated:

> The suggestion that the agency determination must in some way reflect formal, in the sense of properly presented and considered, judgment accords with the rationale underlying the entire series of opinions.

Id. at 159. The Court then ruled:

> It seems clear that the type of informal letter issued by the FDA, apparently without having first conducted any tests, does not constitute the kind of formal or final agency action the Supreme Court had in mind.

Id. at 160.

The *Bentex* and *CIBA* rulings were also the basis for the decision in *Rutherford* v. *United States,* 542 F.2d 1137 (10th Cir. 1976). In *Rutherford,* the Court of Appeals upheld the District Court's preliminary injunction prohibiting FDA from interfering with the interstate shipment of Laetrile and remanded to the District Court with instructions to remand to the agency for an administrative determination of the "new drug" issues. In that suit, FDA had contended it had already determined that Laetrile was a "new drug." The Tenth Circuit reviewed the agency's purported "new drug" determination and stated:

> The FDA has done this without citing any facts whatsoever, merely a conclusion. . . .
>
> * * *
>
> We are unable . . . to see how the FDA can escape the obligation of producing an administrative record to support its determination of the first and more fundamental issue that Laetrile is a *new* drug, for it is not a new drug merely because they say it

> is. Moreover, such a conclusory ruling precludes effective review under 5 U.S.C. Section 706(2). . . .

Id. at 1143 (emphasis in original). In the absence of a reviewable administrative record on the "new drug" issue, the proper course of action was clear to the Court:

> [T]he appropriate procedure for the district court is to remand the case back to the FDA for proceedings adequate to develop a record supportive of the agency's determination; the proceedings should give Laetrile proponents an opportunity to express their views. This is a result which is also supported by the Supreme Court decision in *Weinberger* v. *Bentex Pharmaceuticals*. . . .

Id. at 1143-1144.

The Court of Appeal's conclusion that there is no precedent to support the remand authority is thus plainly incorrect. Indeed, in so arguing it has turned the decisions on their heads. In fact, no court has ever held that a district court lacks such authority and many, including this Court, have affirmed that authority, including the authority to remand in an enforcement proceeding.

Nor does the Court of Appeals' observation that remands are rarely ordered provide any basis for reversing the District Court's orders. Given the clear directives of this Court, it was surely within the District Court's discretion to order a remand under the facts of this particular case.

Perhaps in recognition that its "no one ever does this" rationale would not stand up to scrutiny in light of *Bentex* and *CIBA*, the Court of Appeals sought to bolster its conclusion with two additional arguments. First, it stated that a remand "imposes an administrative burden for which the [FFDCA] makes no provision." App. A, *infra*, 23a. In so stating, it overlooked the

FDA's own regulations[10] and established administrative precedents[11] which clearly contemplate referral by courts and determination by FDA of the "new drug" issues.

Second, while paying lip service to this Court's views on the advantages of seeking FDA's expert judgment on "new drug" issues, the Court below found that such remands are burdensome and time-consuming. App. A, *infra*, 21a-23a. This Court's own words, cited by the District Court in its remand order (App. D, *infra*, 30a-31a), dispose of those arguments:

> We conclude that the District Court's referral of the "new drug" and "grandfather" issues to FDA was appropriate, *as these are the kinds of issues peculiarly suited to initial determination by the FDA*. As the District Court said: "Evaluation of conflicting reports as to the reputation of drugs among experts in the field is not a matter well left to a court without chemical or medical background." The determination whether a drug is generally recognized as safe and effective within the meaning of § 201(p)(1) necessarily implicates complex chemical and pharmacological considerations. *Threshold questions within the peculiar expertise of an administrative agency are appropriately routed to the agency, while the court stays its hand.*

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[10] 21 CFR §10.60 (procedures to handle a referral by a court). *See also* 21 CFR §314.200(e) in which "new drug" and "grandfather" issues are specifically delineated as issues to be addressed in a new drug approval or withdrawal proceeding.

[11] *See*, e.g., 41 Fed. Reg. 14405 (1976), "Drug Products Containing Papaverine or Ethaverine, and Similar or Related Drugs: Request for Data on Safety, Effectiveness, and Legal Status." In that case, the agency called for any data available to support the "old drug" or "grandfather" status of these drugs. If the data submitted failed to show that the product is safe and effective, the April 5 Notice contemplated the publication of an additional notice providing an opportunity for a hearing.

Bentex, supra, 412 U.S. at 653-654 (emphasis added).

Because the Court of Appeals has seriously misconstrued the implications of prior decisons of this Court, it is respectfully suggested that the Court will wish to grant this petition to clarify the meaning of its prior decisions. *See*, e.g., *Securities & Exch. Com'n* v. *United Ben. L. Ins. Co.*, 387 U.S. 202, 207 (1967). Indeed, Alcon submits that the Court of Appeals' unique and aberrant views on the issue of remand in an FFDCA enforcement proceeding call for swift and sure correction by this Court before the decision can be used as precedent to stifle an important, increasingly-used tool for the control by District Courts of the manner and time in which cases on their dockets should be handled.[12]

2. The Decision Below Conflicts With The Decisions Of This Court And Of Another Court Of Appeals Which Indicate That A Court Can Enjoin Further Enforcement Action By The Food And Drug Administration Pending A Remand To That Agency For Determination Of The "New Drug" Issues

In the Court below, Alcon argued that the District Court's order that FDA defer regulatory action pending the remand was non-final and merely an exercise of that Court's discretion to control the case before it. To establish appellate jurisdiction, the FDA argued (and the Court of Appeals agreed) that the order to defer regulatory action was an injunction and so was appealable under 28 U.S.C. §1292(a)(1). App. A, *infra*,

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[12] As will be noted in the discussion of Question 3, *infra*, Alcon seeks review and reversal under 28 U.S.C. §2105 of the appellate court's exercise of jurisdiction over all aspects of the District Court's Orders. A finding by this Court that the Court of Appeals lacked appellate jurisdiction over the Orders would, of course, avoid the necessity of reviewing the merits of the remand issue.

7a-8a. The Court then found the "injunction" improper under *Ewing* v. *Mytinger & Casselberry, Inc.*, 339 U.S. 594 (1950), reading that decision as precluding a district court from enjoining multiple seizure actions under the FFDCA. Moreover, going beyond *Ewing* (yet citing it as authority), the Court of Appeals held that *Ewing* "precludes judicial interference with the FDA's decision to institute enforcement actions, *whatever the precise context.*" App. A, *infra*, 8a (emphasis added). Alcon respectfully submits that the Court below has given an overbroad reading to an older, non-controlling case. Moreover, its decision conflicts with newer decisions of this Court and another Court of Appeals which have squarely sanctioned injunctions against regulatory action pending a remand of the "new drug" issues to FDA's primary jurisdiction.

It is submitted that *Ewing* is not controlling in the circumstances of this case. *Ewing* did not, contrary to the Court of Appeals' interpretation of it, create an absolute prohibition against enjoining the FDA from instituting multiple seizures under any and all circumstances. Rather, *Ewing* held that where the operative statute provides a specific standard for initiating multiple seizures and where the agency has made the requisite findings pursuant to that standard,[13] a court does not have jurisdiction to halt "*all multiple seizures.*" This is to be compared with the instant case where (1) additional seizures based upon the alleged "new drug" status of WANS would not be controlled by a statutory standard or by a requirement for a specific administrative

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[13] The failure of the agency to make these findings would have been sufficient basis under *Ewing* for a court to enjoin multiple seizures.

finding,[14] (2) the District Court's Orders do not purport to halt *all* multiple seizures but rather, at most, only purport to enjoin multiple seizures based upon a "new drug" charge,[15] and (3) the seizure of WANS, whether single or multiple, was contrary to the agency's binding advisory opinion/guideline (the CPG) which, under its specific terms, precluded enforcement action against WANS based upon a "new drug" charge pending the completion of enforcement actions against those drugs identified in the CPG as being subject to a higher enforcement priority.[16] These factors, both individually and collectively, clearly distinguish this case from *Ewing*.[17]

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[14] That portion of 21 U.S.C. §334(a) which was at issue in *Ewing* governs only multiple seizures based upon a misbranding charge and not multiple seizures based upon a "new drug" charge. In the case of a "new drug" charge, unlike a misbranding charge, 21 U.S.C. §334 does not establish a standard defining when multiple seizures are appropriate, nor does it require a probable cause finding by the Secretary of conformity with the standard prior to the initiation of multiple seizures. *See* App. F, *infra,* 37a.

[15] Thus, if at any time the FDA has probable cause to believe that the WANS preparations are "unsafe" or "dangerous to health," the District Court's "injunction" against regulatory action based upon the alleged "new drug" status of WANS would not prevent the agency from relying upon the misbranding and/or adulteration provisions of the FFDCA as the basis for instituting multiple seizures. *See* 21 U.S.C. §§334(a)(1)(B) [App. F, *infra,* 37a-38a], 351(a)(1)(B) [App. F, *infra*, 41a], and 352(j) [App. F, *infra*, 42a].

[16] The Court of Appeals found the CPG inapplicable to WANS (App. A, *infra*, 17a-20a), a proposition Alcon vigorously disputes. Because of the importance of the CPG ruling, it should be considered as part of a review on the merits if the petition is granted.

[17] Nor is the language in *Ewing* that "consolidation . . . is the relief afforded the distributors of the articles" of any comfort to Alcon, as the Court of Appeals believed (App. A, *infra*, 9a). First, there is a significant question whether consolidation is available

It is submitted that, contrary to the Court of Appeals' rulings, neither Congress in enacting the FFDCA nor the Supreme Court in *Ewing* intended to prevent a court from enjoining multiple seizures instituted without factual or legal justification. For example, in *Victrylite Candle Co.* v. *Brannan*, 201 F.2d 206 (D.C. Cir. 1952), the Court of Appeals cited *Ewing* for the proposition that multiple seizures "are not in and of themselves a deprivation of due process" but nevertheless specifically noted that "multiple seizures may be so arbitrarily and destructively engaged in as to amount to a denial of due process, in which event equity may intervene by its injunctive process." *Id.* at 207. *See also National Remedy Co.* v. *Hyde*, 50 F.2d 1066 (D.C. Cir. 1931).

Moreover, while *Ewing* was not controlling below, it is submitted that this Court's *Bentex* ruling was, for it squarely upheld an injunction against regulatory action pending a remand of the "new drug" issues. In that case, the District Court remanded the "new drug" issue to the primary jurisdiction of the FDA for determination, simultaneously enjoining "any action against the [drug company] and their products until [they] had been accorded a hearing before the Secretary on the issue of the qualifications of these drugs for protection under the 'grandfather clause'." *See Bentex Pharmaceuticals, Inc.* v. *Richardson*, 463 F.2d 363, 369 (4th Cir. 1975). The Court of Appeals reversed, ruling that the District Court lacked authority to remand the "new drug" ("grandfather") issue. *Id.* at 371-372. However, the Supreme Court ultimately ruled (as indicated in the discussion of

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under the FFDCA in "new drug" (as opposed to misbranding and adulteration) proceedings. 21 U.S.C. §334(b), App. F, *infra*, 38a. Second, there already has been a consolidation of the first two WANS seizures and this afforded Alcon no relief whatsoever as the agency thereafter instituted a third seizure.

Question 1, *supra*) that the remand power does exist. It therefore reversed the Court of Appeals' decision, thereby reinstating the District Court's injunction against regulatory action pending the remand to FDA. *Weinberger* v. *Bentex Pharmaceuticals, supra*, 412 U.S. at 654 (per Douglas, J., the author of the *Ewing* decision).

Similarly, in *Rutherford* v. *United States, supra*, the Tenth Circuit was called upon to review the District Court's remand of the "new drug" issues to FDA and its injunction against FDA's interference with the shipment of the drug in issue pending the FDA's development of an administrative record during the remand. The Court of Appeals affirmed both the remand and injunction aspects of the lower court's order. 542 F.2d at 1144. It specifically cited the injunction provisions of the Administrative Procedure Act, 5 U.S.C. §705,[18] as authority for continuing the injunction in effect pending the remand.[19]

The *Bentex* and *Rutherford* decisions undoubtedly were predicated upon the realization that, in the absence of an injunction, FDA's unbridled discretion to initiate multiple seizures based upon a "new drug" charge could be used to moot the remand and deny the claimant his day in court. Indeed, Alcon's (and the District Court's) fears that, unless restrained, the FDA would continue conducting crippling, *ex parte* seizures of WANS without awaiting a judicial or administrative resolution of the

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[18] "[T]o the extent necessary to prevent irreparable injury, the reviewing court . . . may issue all necessary and appropriate process to postpone the effective date of an agency action or to preserve status or rights pending conclusion of the review proceedings."

[19] *See also Upjohn Co.* v. *Finch*, 303 F. Supp. 241 (W.D. Mich. 1969).

"new drug" issues seemed to have been borne out by the FDA's third seizure of WANS four days prior to oral argument in the Court of Appeals. It is reflective of FDA's motives underlying this third seizure that, although the Court of Appeals stayed that portion of the Order "enjoining" further new drug seizures on June 23, 1980, FDA did not institute the third seizure action until October 6, 1980. It is submitted that FDA's motive underlying this latest seizure was a tactical decision to influence the outcome of the proceeding in the Court of Appeals and not one predicated upon any concern about the safety of WANS. It must be remembered that the District Court found after reviewing the transcripts of the depositions of the FDA witnesses, as well as other discovery documents, that the FDA's earlier allegations of potential safety problems (allegations which were predicated upon earlier statements of the agency's witnesses) were "contradictory" and "insufficient" to initiate regulatory action under the CPG, a finding which was not challenged by the FDA or the Court of Appeals.

The decision of the Court of Appeals here refusing to uphold the "injunction" pending the remand thus clearly conflicts with the decisions of this Court and of the Tenth Circuit. Additionally, these latter decisions reflect the importance of this Court's considering the remand and injunction issues in tandem for, if the remand order is to be meaningful, a district court must have the discretion to prevent FDA from conducting, as it has here, a destructive series of multiple seizures, thereby unilaterally obtaining a *de facto* injunction against shipment of the drug and depriving the drug company of its day in court.

It is submitted, therefore, that *Ewing* must be read in light of the subsequent cases which, unlike *Ewing*,

dealt specifically with the remand and injunction issues. Indeed, unless *Ewing* is read more narrowly than the Court below reads it, this will mean that the FDA will have absolute discretion to put a company out of business by conducting multiple seizures even where, as here, a district court has found after reviewing the record that the agency's alleged basis for initiating regulatory action was not supported by the facts. In this respect, it is significant that, unlike the factual settings presented in the cases relied upon by the FDA and the Court of Appeals, Alcon did not seek to avoid the initiation of regulatory action by bringing an independent action to enjoin seizures. Rather, it was only after FDA had initiated enforcement action and discovery had shown that these actions were ill-founded that it sought, and the District Court granted, the "remand/injunction" Orders.

Because of the importance of this question in terms of due process for drug manufacturers, and in order to define more precisely what restraints do exist on the exercise of the FDA's discretion under the FFDCA, it is respectfully requested that the Court grant the petition.

3. The Decision Below Violates 28 U.S.C. §2105 and Presents Important Questions Of First Impression Concerning Federal Appellate Jurisdiction Over Orders In Abatement

Alcon argued that the Court of Appeals lacked jurisdiction to review any aspect of the District Court's Orders since they merely abated the actions within the meaning of 28 U.S.C. §2105.[20] That statute provides:

> There shall be no reversal in the Supreme Court or a court of appeals for error in ruling upon matters in abatement which do not involve jurisdiction.

[20] Alcon also argued that the Court of Appeals lacked juridiction in that the orders were not final decisions within the meaning of 28

This statute is a significant (if seldom cited) limitation on federal appellate jurisdiction and should be read in conjunction with the "final order" rule (28 U.S.C. §1291) as expressing a judgment by Congress that the appellate dockets should not be inundated by appeals of patently non-final orders. In a brief and curious footnote, however, the Court of Appeals dismissed Alcon's Section 2105 argument without really addressing it, stating that it would not sustain Alcon's objections to jurisdiction because 2105 "has never been interpreted as a significant limitation on federal appellate jurisdiction . . ." (citing a treatise which states that "the most important feature of § 2105 is certainly its disuse"[21]). In thus trampling upon a significant, if little used, statute governing federal appellate jurisdiction, the Court of Appeals erred and presented this Court with an opportunity to pass on an important question of first impression. *See*, e.g., *American Federation of Musicians* v. *Wittstein*, 379 U.S. 171, 175 (1964).

U.S.C. §1291 nor appealable "collateral orders" within the meaning of *Cohen* v. *Beneficial Industrial Loan Corp.*, 337 U.S. 541 (1949). An analysis of the principles set forth in *Cohen*, as interpreted by more recent decisions of this Court (especially *Firestone Tire & Rubber Co.* v. *Risjord*, 101 S.Ct. 669 (1981)), establishes that the Orders were not collateral orders and that the Court of Appeals' finding to this effect conflicts with a long line of decisions of this Court concerning the definition and applicability of the "collateral order" doctrine. Accordingly, in the event this Court grants the petition it should also consider whether the Court of Appeals committed reversible error in holding that under the collateral order exception to 28 U.S.C. §1291 it had jurisdiction to review the District Court's Orders.

[21] 15 Wright, Miller, & Cooper, FEDERAL PRACTICE AND PROCEDURE §3903, at 414 (1976).

The remand Orders clearly effected an abatement of the actions before the District Court.[22] "Abatement," as several decisions have noted in reviewing Section 2105, is the overthrow of an action which defeats the action for the present, but does not debar the plaintiff from commencing it in a better way. *Aetna State Bank* v. *Altheimer*, 430 F.2d 750, 753-754 (7th Cir. 1970); *Bowles* v. *Wilke*, 175 F.2d 35, 37 (7th Cir. 1949). Abatement in equity (such as obtains here since FDA sought an injunction) is an interruption or suspension of a suit which is brought about by the defendant setting up facts in abatement. 1 C.J.S. *Abatement and Revival* §1, at 27 (1936). Equitable abatement is analogous to a plea in suspension in which the defendant shows some ground for not proceeding with the suit at the present time and prays that the proceeding be stayed until the ground is removed. 1 C.J.S. *Abatement and Revival* §7, at 36. *See* 1 AM. JUR. 2d *Abatement, Survival, and Revival* §1, at 42 (1962). Alcon's Motion to Remand meets all of these criteria.

Reviewing Section 2105, the Court of Appeals found that the District Court's Orders involved jurisdiction, citing *Aetna*, *supra* at 653, and therefore came within an exception to Section 2105. While there is some confusing dictum in *Aetna* suggesting that Section 2105 may be inapplicable when another federal statute specifically grants jurisdiction, that language is not controlling here. The FFDCA provides no specific appellate jurisdiction over a "new drug" remand order and so is distinguishable from the *Aetna* facts. Moreover, *Aetna* involved abstention by a federal court in a matter involving mixed federal/state issues, in which the federal court

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[22] The Court of Appeals did not even address this basic issue, instead "Passing by the question whether this action is in abatement. . . ." App. A, *infra*, 15a n.2.

dismissed the federal action entirely. Here, the District Court specifically retained jurisdiction over the whole matter pending the remand to FDA's primary jurisdiction. As Professors Wright, Miller, and Cooper state in analyzing Section 2105, a remand to an agency's primary jurisdiction is a typical example of a "matter[ ] in abatement which do[es] not involve jurisdiction." 15 Wright, Miller, & Cooper, FEDERAL PRACTICE AND PROCEDURE §3903, at 414.

The Court of Appeals also argued somewhat lamely that "our disposition of the case is not, technically, a 'reversal'. . ." as that term is used in Section 2105. However, it is difficult, if not impossible, to identify any proposition of law or fact proffered by Alcon or relied upon by the District Court which the Court of Appeals did not reverse.

In short, the Court of Appeals' ruling on Section 2105 constituted manifest error. In refusing to apply the language of that statute to a situation so obviously within the reach of the statute, the Court so far departed from the accepted and usual course of judicial proceedings as to call for the immediate exercise of this Court's power of supervision. That a statute is rarely invoked in no way detracts from the fact of its existence or from the duty of a court to enforce it. That a statute is even less frequently relied upon to limit federal appellate jurisdiction should in no way deter courts with crowded dockets from using it in appropriate circumstances, thereby effectuating the Congressional purpose of limiting federal appellate jurisdiction to truly final decisions of the District Courts.[23]

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[23] Because of the manifest error of the Court of Appeals in refusing to decline jurisidiction under 28 U.S.C. §2105, this Court may wish to consider summary reversal of the Court of Appeals' opinion and reinstatement of the District Court's Orders.

CONCLUSION

For these reasons, a writ of certiorari should issue to review the opinion and judgment of the United States Court of Appeals for the First Circuit. The Court may wish to consider summary reversal on the basis of 28 U.S.C. §2105.

Respectfully submitted,

THOMAS O. HENTELEFF
GLENN E. DAVIS

Counsel for Petitioners

Of Counsel:

MANUEL A. GUZMAN
PETER R. MATHERS

March 23, 1981

APPENDIX

APPENDIX A

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

Nos. 80-1188, 1357

(Decided February 24, 1981)

UNITED STATES OF AMERICA,

v.

ALCON LABORATORIES, ETC., *et al.*,

Before COFFIN, *Chief Judge,*
PELL* and CAMPBELL, *Circuit Judges.*

OPINION

CAMPBELL, *Circuit Judge.* The United States appeals from orders of the District Court for the District of Puerto Rico in two seizure actions and a suit for injunctive relief instituted by the Food and Drug Administration (FDA) against Alcon Laboratories, Inc. (Alcon) and one of its products pursuant to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§301-92 (1976).

Alcon manufactures and markets in suppository dosage a prescription antiemetic drug called "WANS." The drug contains pyrilamine maleate (an antihistamine) and pentobarbital sodium (a barbituate [*sic*]) and comes in three dosage strengths, WANS No. 1, WANS No. 2 and WANS Children. WANS has been used under medical supervision for approx-

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*Of the Seventh Circuit, sitting by designation.

imately 25 years, and did not become an object of FDA concern until 1978. To understand what then transpired, it is first useful to review parts of the Federal Food, Drug, and Cosmetic Act.

Section 505 of the Act forbids the introduction into interstate commerce of any "new drug" unless the FDA has approved a New Drug Application (NDA) for the product. 21 U.S.C. § 355. Section 201(p) defines a "new drug" as

> "(1) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, . . . or
>
> (2) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions."

21 U.S.C. §321(p). Obtaining approval of an NDA requires the submission of extensive scientific data and can be slow and expensive, *see* Note, New Drug Approval: *Lannett,* The Drug Lag and the NDA System, 11 Rut.-Cam. L.J. 231-34; 248-53 (1980), but Congress imposed these burdens in furtherance of a compelling purpose: "to protect the public against danger to human life arising from use of unsafe and ineffective drugs by assuring that before any drug is marketed it will have been carefully reviewed by FDA experts." *Premo Pharmaceutical Laboratories, Inc.* v. *United States,* 629 F.2d 795, 802 (2d Cir. 1980).

A product may be marketable without prior FDA approval for any of three reasons. First, a drug is not a "new drug" if "generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof"; if this "expert consensus is founded upon 'substantial evidence' "; *and* if the drug has "been used to a material extent or for a material time under such conditions." 21 U.S.C. § 321(p); *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 631-32 (1973); *Premo Pharmaceutical, supra,* 629 F.2d at 801-02. Second, under a "grandfather" clause inserted in the 1938 Act, drugs which prior to June 25, 1938 (the effective date of the Act) were "subject to the Food and Drugs Act of June 30, 1906" and have since undergone no change in composition, labelling or recommendations for use are exempt from Section 505's premarketing approval requirements. 21 U.S.C. § 321(p)(1). And third, another grandfather clause in the Act, added in 1962, relieves from premarketing approval any drug which prior to October 10, 1962 (the effective date of the 1962 amendments) "was commercially used or sold in the United States," was generally recognized as safe by qualified experts, was not covered by an effective new drug application and has undergone no change in composition or labeling. Comment to 21 U.S.C. § 321.

Where the FDA believes that a drug is a "new drug" and is being marketed without approval of an NDA, it is empowered to institute seizure and injunction actions in federal district court to remedy the alleged violation of the Act. 21 U.S.C. §§ 332, 334. The agency may also seek criminal sanctions. 21 U.S.C. § 333.

On March 17, 1978, the FDA sent Alcon a regulatory letter informing it of a report received from the agency's Neurological Drugs Advisory Committee "that children aged 6 months to seven years who were treated for nausea and vomiting with drugs containing pyrilamine maleate and pen-

tobarbital, experienced severe and sometimes fatal reactions." The Committee had concluded, the letter went on, "that there is no evidence of safety and efficacy for drugs containing pyrilamine maleate with or without a barbituate [*sic*] in the treatment of nausea and vomiting." Based on the Committee's report, "and because [the FDA was] unaware of substantial scientific evidence which demonstrates that a combination of these ingredients is generally recognized as safe and effective for the treatment of nausea and vomiting," the FDA advised Alcon that it considered Alcon's marketing of WANS to be in violation of the "new drug" provision of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355. The letter stated that under FDA regulatory policy as formulated in Compliance Policy Guide 7132c.08, *see infra,* WANS had become subject to immediate regulatory action outside the agency's ordinary enforcement priorities "because of new information concerning the safety and efficacy of these drugs." Alcon was told to reply within ten days, and was warned that failure to discontinue marketing WANS would expose the company to seizure and injunction actions.

Alcon responded on April 3, 1978. It claimed that WANS was not a "new drug," objected to the FDA's departure from the ordinary sequence of its enforcement priorities on the basis of an "unsubstantiated, conclusionary indictment of the safety" of the active ingeedients in WANS, and requested that it be allowed to "identify and review the data and information upon which the Agency relies, and to make a formal submission to the Agency. . . ." The company also offered to revise the labeling of WANS consistent with the findings of its review. Subsequent to this letter, Alcon, on its own initiative, sent the FDA proposed new labeling for WANS and information supporting the safety and efficacy of the drug. Various company officials met with agency officials on July 10 and 18, 1978 to discuss WANS.

The FDA reviewed the materials provided by Alcon and in a letter of August 4, 1978 reaffirmed its position upon the "new drug" status of WANS: "the data submitted . . . con-

tains no adequate scientific data to support the safety and efficacy of the Wans products." Though the proposed relabeling was felt to be "an improvement," it could not substitute for "scientific evidence to establish that a fixed combination of pyrilamine maleate and pentobarbital sodium is either safe or effective for the treatment of nausea and vomiting." The letter made no reference to Compliance Policy Guide 7132c.08 or to the enforcement priority scheme delineated therein.

Alcon continued to manufacture WANS and on September 21, 1978 the FDA instituted a seizure action in federal district court alleging that the drug was a "new drug" being marketed in violation of Section 505 of the Act, 21 U.S.C. § 355. By court order, a large quantity of WANS suppositories (approximately 453,900) was seized. In its responsive pleadings in the seizure action, Alcon admitted that no approval of a new drug application was in effect for WANS or was being sought. The company nevertheless denied that WANS was being marketed in violation of section 505. Alcon argued that WANS is not subject to the "new drug" requirements of the Act because "it is generally recognized as safe for use under the conditions prescribed, recommended or suggested in its labeling, and it is exempted from the 'efficacy' requirements of the Federal Food, Drug and Cosmetic Act" by the 1962 grandfather clause discussed *supra*. In addition, Alcon contended that the FDA was acting in violation of its pertinent Compliance Policy Guide.

Despite seizure of the suppositories, Alcon continued to manufacture and distribute WANS, thus prompting the FDA, on November 28, 1978, to institute a further action, this time seeking a temporary restraining order, a preliminary injunction and a permanent injunction against continued marketing of WANS without FDA approval. On the next day, November 29, the district court denied the FDA's request for a temporary restraining order, and consolidated the injunctive suit with the earlier seizure action. On December 19, 1978, the district court gave the parties 90 days to complete discovery in the consolidated proceeding and set a trial date of May 7, 1979.

On March 21, 1979, however, Alcon moved the district court to remand to the FDA,

> "with instructions to defer regulatory action against the WANS preparations involved in this matter or against defendants based upon the alleged 'new drug' status of WANS until FDA makes an administrative determination of the new drug status of WANS in conformity with the enforcement priorities enunciated in FDA's Compliance Policy Guide 7132c.08 and the requirements of the Administrative Procedure Act, or unless verifiable and genuinely significant and new information surfaces which questions the safety or efficacy of a WANS preparation so as to justify taking regulatory action against such preparation out of the sequence provided by the Agency's Compliance Policy Guide 7132c.08."

No further action was taken in the case until January 28, 1980. On that date the FDA instituted a second seizure against WANS. Large quantities of the drug were again confiscated. A month later, on February 27, 1980, the district court consolidated the latest seizure action with the pending actions, and ordered the entire case to be,

> "remanded to the Food and Drug Administration (FDA) with instructions to defer regulatory action against the WANS preparations involved in this matter or against defendants based upon the alleged 'new drug' status of WANS until FDA holds a hearing pursuant to 5 U.S.C. § 554 and thereafter makes an administrative determination of the new drug status of WANS in conformity with the enforcement priorities enunciated in FDA's Compliance Policy Guide 7132c.08.
>
> "Accordingly, it is FURTHER ORDERED
>
> "That prior seizures ordered by the Court are left without effect.
>
> "However, jurisdiction will be retained whether new, verifiable and genuinely significant information comes to light which questions the safety or efficacy of a WANS

> preparation so as to justify enforcement action against such preparation out of the sequence provided by the Agency's Compliance Policy Guide 7132c.08."

On April 8, 1980, the district court issued an Opinion and Order explaining and reiterating this order. We treat the two orders, which are the same but for their date of issuance, as a single order.

The United States filed separate appeals from the orders of February 27 and April 8, and these have been consolidated. The United States also moved for, and we have granted, a stay pending appeal with respect to the district court's order enjoining future seizures, and ordering the return of quantities of the drug already seized.

The United States presently attacks three aspects of the district court's order: (1) its instruction that the FDA "defer regulatory action against the WANS preparation . . . or against defendants" pending further administrative proceedings; (2) its decision to leave prior seizures of WANS "without effect"; and (3) its remand of the case to the agency. We consider these issues in turn; and in connection with each we also address this court's appellate jurisdiction.[1]

The Order To "Defer" Regulatory Action

Our jurisdiction to review the district court's interlocutory order that the FDA defer further regulatory action against WANS and Alcon depends on whether the order is appealable as one granting an injunction, *see* 28 U.S.C. §1292(a)(1), or is simply, as Alcon contends, an exercise of the court's discretion in controlling a case before it. Looking to the order's "substantial effect," *see United States* v. *Cities Service Co.*, 410 F.2d 662, 663 n.1 (1st Cir. 1969); *Hotel & Restaurant Employees and Bartenders International Union* v. *Del Valle*, 328 F.2d 885, 886 (1st Cir.), *cert. denied*, 379 U.S.

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[1] Alcon has moved for summary dismissal of the government's appeals, asserting lack of appellate jurisdiction. We advised that we would consider the motion when deciding the merits.

879 (1964), we think it was an injunction, hence appealable under section 1292(a)(1). The order has the effect of forbidding the FDA from exercising in any forum its statutory power both to proceed against WANS and its producer and to seize the article pending condemnation. Absence of the word "enjoin" does nothing to mitigate the blanket severity of the decree. Whether regulatory action against a possibly unsafe or ineffective drug must be "deferred" or is "enjoined" is a matter of semantics. In either case, the agency is denied the ability to take summary steps to protect those to whom the drug will be distributed in the interim.

This injunction exceeded the district court's authority. To prevent this sort of eroding of the agency's protective powers, the Supreme Court in *Ewing* v. *Mytinger & Casselberry, Inc.*, 339 U.S. 594 (1950), held that district courts lack jurisdiction to enjoin multiple seizure actions instituted by the FDA under the Act. The rule of *Ewing* has been consistently and strictly observed, *see Southeastern Minerals, Inc.* v. *Harris*, 622 F.2d 758 (5th Cir. 1980); *Pharmadyne Laboratories, Inc.* v. *Kennedy*, 596 F.2d 568 (3d Cir. 1979); *Parke, Davis & Co.* v. *Califano*, 564 F.2d 1200 (6th Cir. 1977), *cert. denied*, 435 U.S. 942 (1978); *Natick Paperboard Corp.* v. *Weinberger*, 498 F.2d 125 (1st Cir. 1974), *cert. denied*, 429 U.S. 819 (1976), and controls the present case. We see no distinction between this case and *Ewing* merely because the latter involved multiple seizures for alleged misbranding, which may be instituted only when there is probable cause to believe that the article is dangerous or that the misbranding may be fraudulent or misleading. Risks to consumers may be present in new drug cases, and the same section of the Act is involved. *See* 21 U.S.C. § 334(a)(1). The Supreme Court's decision in *Ewing* precludes judicial interference with the FDA's decision to institute enforcement actions, whatever the precise context. *Compare Southeastern Minerals, supra*, 622 F.2d at 763-64 *with Parke, Davis & Co., supra*, 564 F.2d at 1205 *and Natick Paperboard, supra*, 498 F.2d at 126-27. Alcon's argument that such a rule exposes a manufacturer to potentially devastating

hardship and loss was disposed of in *Ewing*. *See* 339 U.S. at 604-05 (Jackson, J., dissenting). The considerations from which the *Ewing* holding emerged dictate that it be applied and that the district court's order, insofar as it bars initiation of further FDA enforcement actions, be vacated:

> "The purpose of the multiple seizure provision is plain. It is to arrest the distribution of an article that is dangerous, or whose labeling is fraudulent or misleading, pending a determination of the issue of adulteration or misbranding. The public therefore has a stake in the jurisdictional issue before us. If the District Court can step in, stay the institution of seizures, and bring the administrative regulation to a halt until it hears the case, the public will be denied the speedy protection which Congress provided by multiple seizures.
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> * * *
>
> "The means which Congress provided to protect consumers against the injurious consequences of protracted proceedings would then be seriously impaired. Congress weighed the potential injury to the public from misbranded articles against the injury to the purveyor of the article from a temporary interference with its distribution and decided in favor of the speedy, preventive device of multiple seizures. We would impair or destroy the effectiveness of that device if we sanctioned the interference which a grant of jurisdiction to the District Court would entail. Multiple seizures are the means of protection afforded the public. Consolidation of all the libel suits so that one trial may be had is the relief afforded the distributors of the articles."

339 U.S. at 601-02 (footnotes omitted). *See also Premo Pharmaceutical, supra,* 629 F.2d at 801; *Natick Paperboard, supra,* 498 F.2d at 127.

The Dissolution Of Prior Seizures

We agree with the United States that so much of the district court's order as purports to leave the FDA's former seizures "without effect" is appealable as a collateral order. *See Cohen* v. *Beneficial Industrial Loan Corp.*, 337 U.S. 541 (1949), discussed *infra* in connection with the remand order. The present situation is like that in *Swift & Co. Packers* v. *Compania Colombiana Del Caribe,* 339 U.S. 684 (1950), where the *Cohen* rule was held to apply. The Supreme Court there stated,

> "Appellate review of the order dissolving the attachment at a later date would be an empty rite after the vessel had been released and the restoration of the attachment only theoretically possible. Under these circumstances the provision for appeals only from final decisions in 28 U.S.C. § 1291 should not be construed so as to deny effective review of a claim fairly severable from the context of a larger litigious process."

339 U.S. at 689 (citations omitted). The same can be said as to the futility of later appellate review of this order requiring, it would seem, immediate release of the seized suppositories. We therefore turn to the merits of the present appeal.

It is the government's contention that the district court "ha[d] no authority simply to give back the seized property without determining . . . whether or not the Act [was] violated." The Act provides that before trial the court shall "allow any party to a condemnation proceeding . . . to obtain a representative sample of the article seized" and that after condemnation the court has discretion to order the goods sold or destroyed, 21 U.S.C. § 334(c),(d), but otherwise is silent upon the release of seized goods prior to a decision upon the FDA's claims. Rule E(5)(c) of the Supplemental Rules for Certain Admiralty and Maritime Claims, which were intended to inform seizure procedure under the Act, *see* 21 U.S.C. § 334(b), states that seized property held by the marshal

> "may be released forthwith upon his acceptance and approval of a stipulation, bond, or other security, signed by

> the party on whose behalf the property is detained or his attorney and expressly authorizing such release, if all costs and charges of the court and its officers shall have first been paid. Otherwise no property in the custody of the marshal or other officer of the court shall be released without an order of the court; but such order may be entered as of course by the clerk, upon the giving of approved security as provided by law and these rules, or upon the dismissal or discontinuance of the action; but the marshal shall not deliver any property so released until the costs and charges of the officers of the court shall first have been paid."

Alcon contends that this portion of Rule E(5) implies some general grant of authority to a court to order the release of seized property. However, the purpose and focus of Rule E(5) is merely to describe the circumstances under which seized property may be released prior to a court's determination of the merits: thus it provides for release of property if a plaintiff consents, or when "approved security as provided by law and these rules" is tendered. Neither circumstance exists here (and, indeed, in a new drug case, where the purpose of the seizure is to remove a possibly risky drug from public use, it is hard to see how the mere putting up of security would be a proper basis for release). In any event, we see little in Rule E(5) by way of a general grant of authority permitting courts to countermand administratively instituted seizures without first adjudicating the merits of the agency's claim. If the seizure is plainly frivolous, the court can act rapidly and achieve justice in that manner, but its action should ordinarily follow, not precede, an adjudication. We have found only two cases that bear on the question. One holds, and the other suggests, that articles seized in an FDA enforcement action may not be released by the court prior to a judicial determination of whether they violate the Act. *See In re United States,* 140 F.2d 19 (5th Cir. 1943); *United States* v. *893 One-Gallon Cans . . . Brown's Inhalant,* 45 F.Supp. 467 (D. Del. 1942).

We conclude that the district court erred in dissolving the administrative seizures of WANS without first addressing the merits of the seizure proceedings initiated by the FDA, including, as part thereof, the agency's contention that WANS is a "new drug." We therefore vacate this portion of the district court's order. The district court believed that allowing "the continued retention of the material seized would be an abuse of judicial discretion" in light of its findings that WANS "has been used for years" and that "the information which prompted the F.D.A. to initiate these actions was not only contradictory, but also insufficient to allow a causal relation." These preliminary and necessarily tentative and incomplete findings cannot serve as a substitute for a determination on the merits. It has been said that in pursuing a seizure action, the FDA must first allege sufficient facts to state a claim and must then prove its claim by a preponderance of the evidence. *See United States* v. *47 Bottles . . . "Jenasol RJ Formula '60' "*, 320 F.2d 564, 569-71 (3d Cir.), *cert. denied,* 375 U.S. 953 (1963); *United States* v. *4 Cases . . . Slim-Mint Chewing Gum,* 300 F.2d 144, 148-50 (7th Cir. 1962). A decision by a district court as to whether the FDA has met those burdens would be the proper means for adjudicating the validity of the FDA's enforcement efforts; a seizure should only be dissolved thereafter, in event of the government's failure to do so.

The Remand To The FDA

Remand of a case for further proceedings is ordinarily not appealable in that it is not a "final decision" from which appeals may be taken under 28 U.S.C. § 1291. *See Pauls* v. *Secretary,* 457 F.2d 294 (1st Cir. 1972). The government, however, argues that the district court's order in this case is appealable under section 1291 as a collateral order within the meaning of *Cohen* v. *Beneficial Industrial Loan Corp., supra,* 337 U.S. 541.

In *Cohen,* the Supreme Court held that a district court's refusal to order the plaintiff in a stockholders' derivative suit

to post security for costs as required by a state statute was immediately appealable because it fell in "that small class" of decisions "which finally determine claims of right separable from, and collateral to, rights asserted in the action, too important to be denied review and too independent of the cause itself to require that appellate consideration be deferred until the whole case is adjudicated." 337 U.S. at 546. We have interpreted the Court's formulation in *Cohen* to require that appealability be predicated on four characteristics:

> "The order must involve: (1) an issue essentially unrelated to the merits of the main dispute, capable of review without disrupting the main trial; (2) a complete resolution of the issue, not one that is 'unfinished' or 'inconclusive'; (3) a right incapable of vindication on appeal from final judgment; and (4) an important and unsettled question of controlling law, not merely a question of the proper exercise of the trial court's discretion."

United States v. *Sorren,* 605 F.2d 1211, 1213 (1st Cir. 1979), *quoted in In re Continental Investment Corp.,* No. 80-1362, slip op. at 6 (1st Cir. Oct. 31, 1980). The requisites may be summarized as separability, finality, urgency, and importance. *In re Continental Investment Corp., supra,* slip op. at 6. *Cf. Grinnell Corp.* v. *Hackett,* 519 F.2d 595, 596 (1st Cir.), *cert. denied sub nom. Chamber of Commerce* v. *United Steelworkers,* 423 U.S. 1033 (1975) (arguing that "urgency" necessarily subsumes "finality"). *See generally Firestone Tire & Rubber Co.* v. *Risjord,* 49 U.S.L.W. 4089, 4090-92 (Jan. 13, 1981). We find each characteristic to be present here and so hold that the order is appealable.

First, the remand order raises issues that are entirely separable from the ultimate question to be decided by this litigation, the "new drug" status of WANS. In remanding, the court ordered the FDA to hold "a hearing pursuant to 5 U.S.C. § 554 and thereafter make[ ] an administrative determination of the new drug status [of] WANS in conformity with the enforcement priorities enunciated in FDA's Compliance Policy Guide 7132c.08." The decree thus implicates

the power of the agency to summarily initiate enforcement proceedings under the Act and its own regulations. It also puts at issue the manner in which FDA enforcement actions ought to proceed. These issues are independent of the merits of the underlying claim against WANS. *See Lopez* v. *Secretary,* 512 F.2d 1155 (1st Cir. 1975) (allowing appeal from remand requiring Secretary of HEW to show claimant had a "realistic opportunity" of being hired for available positions); *Gueory* v. *Hampton*, 510 F.2d 1222, 1224-25 (D.C. Cir. 1975) (allowing appeal from remand that required Civil Service Commission to show how conduct for which employee was dismissed had diminished the efficiency of the service); *Gold* v. *Weinberger,* 473 F.2d 1376, 1378 (5th Cir. 1973) (allowing appeal from remand holding that Secretary of HEW could not prove availability of reasonable job opportunities by testimony of vocational expert who had not interviewed claimant); *Cohen* v. *Perales,* 412 F.2d 44 (5th Cir. 1969), *rev'd on other grounds sub nom. Richardson* v. *Perales,* 402 U.S. 389 (1971) (allowing appeal from remand establishing agency standards for the admission of hearsay evidence and holding that hearsay evidence is not substantial evidence to support agency decision).

Second, the district court's order is final as to these issues. There are no further steps that the government can take to avoid imposition of the procedural requirements it seeks to challenge here. *See Abney* v. *United States,* 431 U.S. 651, 659 (1977). The district court has unambiguously declared in an order, a subsequent opinion and a denial of a stay motion that it will take no further actions pending FDA compliance with its decree. Its order therefore cannot realistically be characterized as not final because subject to revision. *Compare Coopers & Lybrand* v. *Livesay,* 437 U.S. 463, 469 (1978); *Eluska* v. *Andrus,* 587 F.2d 996, 1001 (9th Cir. 1978). The district court's retention of jurisdiction over the case does not affect the finality of its order. *Compare United Transportation Union* v. *Illinois Central R.R.,* 433 F.2d 566, 568 (7th Cir. 1970), *cert. denied,* 402 U.S. 915

(1971), *with Transportation-Communication Division, Brotherhood of Railway, Airline & Steamship Clerks* v. *St. Louis-San Francisco Ry.*, 419 F.2d 933, 936 (8th Cir. 1969), *cert. denied,* 400 U.S. 818 (1970).

Third, review of the remand order is urgent, for if we lack jurisdiction now over the questions presented, it seems improbable that they will ever be subject to review. *Compare Gueory, supra,* 510 F.2d at 1225 *and Gold, supra,* 473 F.2d at 1378 *and Perales, supra,* 412 F.2d at 48 *with Coopers & Lybrand, supra,* 437 U.S. at 469 *and Loya* v. *INS,* 583 F.2d 1110 (9th Cir. 1978) *and Barfield* v. *Weinberger,* 485 F.2d 696 (5th Cir. 1973).

Fourth and finally, the characteristic of importance is also present here.

> "Importance in this context refers to the scope of precedential value — to whether a case presents 'an important and unsettled question of controlling law', *United States* v. *Sorren, supra,* 605 F.2d at 1213, a decision as to which 'will settle the matter not simply for the case at hand but for many others', *Grinnell Corp.* v. *Hackett, supra,* 519 F.2d at 597."

Continental Investment Corp., supra, slip op. at 9. The government's appeal does not merely challenge an exercise of the district court's discretion, *see In re Grand Jury Proceedings,* 580 F.2d 13, 17 (1st Cir. 1978); instead, it raises broader questions of how FDA enforcement actions are to proceed. Resolution of these questions is important both to the future FDA regulatory efforts and to the public, whose safety may depend upon those efforts. We therefore proceed to the merits of the government's contentions.[2]

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[2] As to the appeal in general, Alcon argues that we are deprived of jurisdiction by 28 U.S.C. § 2105, which provides

> "There shall be no reversal in the Supreme Court or a court of appeals for error in ruling upon matters in abatement which do not involve jurisdiction."

Passing by the question whether this action is in abatement, we note that the district court's remand order can be understood as

The district court premised its decision to remand to the FDA on interrelated procedural and substantive grounds. The court was troubled by the agency's failure to conduct "a formal administrative determination of the 'new drug' status of WANS" before instituting suit against Alcon. In the absence of such a determination, the court felt that an FDA internal regulation — Compliance Policy Guide 7132c.08 — precluded enforcement action against WANS unless the agency possessed "significant new information which questions the safety of the drug." However, the court characterized itself as ill-suited to decide the "new drug" status of WANS or to determine whether "significant new information" existed that questioned WANS' safety. Citing lack of jurisdiction, the doctrine of primary agency jurisdiction and prudential considerations, the court decided that these questions were better left to "the Agency entrusted by Congress with the necessary expertise to make a responsible determination." Accordingly, it ordered the action "remanded to the Food and Drug Administration to hold a formal administrative hearing pursuant to 5 U.S.C. § 554 on the issue as to whether WANS is a 'new drug' in conformity with the enforcement priorities enunciated in F.D.A.'s Compliance Policy Guide 7132c.08."

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involving jurisdiction, *see Aetna State Bank* v. *Altheimer,* 430 F.2d 750, 753 (7th Cir. 1970), and our disposition of the case is not, technically, a "reversal," *see* 15 Wright, Miller & Cooper, *Federal Practice & Procedure: Civil* § 3903, at 414-15 (1976). In any event, despite its plain language section 2105 has never been interpreted as a significant limitation on federal appellate jurisdiction:

> "The most important feature of § 2105 is certainly its disuse.
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> * * *
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> "[A]ppellate review . . . is notoriously frequent with respect to such problems as abstention of federal decision in deference to state proceedings, deferral of judicial decision pending resort to the 'primary jurisdiction' of administrative agencies, or a requirement that private grievance proceedings be exhausted before seeking judicial interference in labor-management relations."

15 Wright, Miller & Cooper, *supra,* § 3903, at 414.

The court's concern over summary institution of enforcement proceedings is shared by some in the drug industry, *see* Swire, FDA's Multiple Seizure Powers: A Time for Equity, 34 Food, Drug, Cosmetic L.J. 244 (1979), but the imposition of a pre-enforcement hearing requirement (coupled with preliminary relief, as, to be meaningful, it would have to be) is at odds with the language and intent of the Act. To be sure, in certain circumstances a formal administrative proceeding is a precondition to agency action. For example, when the FDA issues, pursuant to 5 U.S.C. § 554(e), a declaratory order governing all drugs covered by a particular new drug application, or when it withdraws approval of a new drug application pursuant to 21 U.S.C. § 355(e), it must first hold a hearing in compliance with section 554 of the Administrative Procedure Act, 5 U.S.C. § 554. *See Hynson, supra,* 412 U.S. at 620, 625. Each action is a "case of adjudication required by statute to be determined on the record after opportunity for an agency hearing" for purposes of the APA, 5 U.S.C. § 554(a). *See* 5 U.S.C. § 554(e) (declaratory order); 21 U.S.C. § 355(e) (withdrawal of NDA). By contrast, there is no statutory hearing requirement for FDA decisions to initiate seizure or injunction actions. *See* 21 U.S.C. §§ 332, 334. Indeed, the probable cause determination necessary to institute multiple seizure actions against allegedly misbranded products is to be made "without hearing." 21 U.S.C. § 334(a)(1). As the Supreme Court has made abundantly clear, a manufacturer subjected to an FDA enforcement action has no right to raise objections in an administrative forum prior to the agency's institution of the action. *See Ewing, supra,* 339 U.S. 594. *Cf. Abbott Laboratories* v. *Gardner,* 387 U.S. 136, 146-48 (1967) (reaffirming *Ewing* and distinguishing it from declaratory action brought by drug manufacturers challenging FDA regulations prior to their enforcement). This is because the imposition of any formal, pre-enforcement hearing requirement might seriously impair the effectiveness of the Act's enforcement provisions. *See id.*

The district court's concern that the FDA might be proceeding in violation of its own internal regulatory guidelines

was also in error. Compliance Policy Guide 7132c.08 establishes FDA enforcement priorities for specific types of drugs, *see infra,* and declares that the FDA will depart from those priorities only under specified circumstances, one being receipt of "significant new information which questions the safety or effectiveness of the drug." A brief review of the history[3] and text of Compliance Policy Guide 7132c.08, however, demonstrates that the guideline does not apply to WANS.

Under the 1938 Federal Food, Drug, and Cosmetic Act, a drug had only to be proven safe to be approved by the FDA for interstate marketing. Approval of a new drug application was automatic within a fixed period after submission unless the FDA in the interim affirmatively disapproved it. The 1962 amendments to the Act substantially modified these premarketing clearance procedures. A "new drug" was redefined to be one not generally recognized among experts as *effective* as well as safe, and the automatic approval of new drug applications was eliminated. A "new drug" therefore could not be lawfully marketed unless it satisfied both the safety *and* effectiveness requirements of the Act and had been affirmatively approved by the FDA. These changes presented the FDA with an enormous problem: By virtue of the 1962 amendments thousands of drugs with NDA's already approved for safety, but not effectiveness ("pioneer" drugs), and many more thousands of drugs considered generically identical to already approved drugs ("me-too" drugs), became "new drugs" subject to the agency clearance procedure of

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[3] Our discussion draws on several sources: *United States* v. *Lannett Co.,* 585 F.2d 575 (3d Cir. 1978); *Hoffmann-LaRoche, Inc.* v. *Weinberger,* 425 F. Supp. 890 (D.D.C. 1975); Fleshner, *Lannett,* Premarketing Clearance and "Me-Too" Drugs; Where Do We Go From Here?, 35 Food, Drug, Cosmetic L.J. 44 (1980); Note, Regulating Laetrile: Constitutional and Statutory Implications, 5 U. Dayton L. Rev. 155 (1980); Note, New Drug Approval: *Lannett,* The Drug Lag, and the NDA System, 11 Rut.-Cam. L.J. 231 (1980).

section 505 of the Act, 21 U.S.C. § 355. To speed its newly created job of determining the effectiveness of these drugs, the FDA arranged to have the National Academy of Sciences-National Research Council conduct a Drug Efficiency [*sic*] Study of nearly 4,000 drugs. The results of this study were incorporated into Drug Efficiency [*sic*] Study Implementation (DESI) notices that indicated whether or not the FDA considered particular drugs to be effective. All distributors of drugs covered by a DESI notice and not holding an approved new drug application were variously required to submit either a full or abbreviated new drug application. However, upon submission and prior to approval of the required application, manufacturers of me-too drugs were permitted to market their products if a full new drug application had already been approved for the related pioneer drug. This approach to the administrative problems created by the 1962 amendments was struck down in *Hoffmann-LaRoche, Inc.* v. *Weinberger,* 425 F. Supp. 890 (D.D.C. 1975), which held that *no* new drug — pioneer or me-too — could be introduced into interstate commerce without its new drug application having first been approved by the FDA.

Compliance Policy Guide 7132c.08 is the FDA's attempt to incorporate into the DESI program the holding of *Hoffmann-LaRoche.* Recognizing that independent evaluation of the effectiveness of all DESI drugs will unavoidably delay achievement of industry-wide compliance with the Act, the Guide sets out "a strategy to deal on a priority basis with those drugs which most affect public health and safety[,] to provide equitable treatment among competing firms, and to have a maximum impact on violative products." It establishes FDA enforcement priorities according to two general groups of drugs: "DESI prescription drugs where a final determination on effectiveness has been made" and "DESI and other prescription drugs where a final determination on effectiveness has not been made." Each group is further divided into several smaller categories.

WANS is not covered by Compliance Policy Guide 7132c.08 because it is not part of the DESI program. As Alcon expressly acknowledges, WANS is neither a pioneer drug (it is not covered by a pre-1962 NDA) nor a me-too drug (it is not generically identical to a pioneer drug). To read the phrase "other prescription drugs where a final determination on effectiveness has not been made," *supra,* as including WANS would impermissibly extend the Compliance Policy Guide far beyond its historic context and purpose. The proper scope of the second group of drugs defined by the Compliance Policy Guide is illustrated by its three subcategories, none of which applies to WANS. It is true, as Alcon points out, that the FDA's initial regulatory letter described WANS as falling under this category, but later correspondence omitted this reference. In any event, Alcon does not claim that what the government concedes to have been an unfortunate mistake might now estop it from correctly treating WANS as a drug not covered by the Guide. The district court was thus in error to require that the FDA comply with Compliance Policy Guide 7132c.08 and withhold regulatory action against WANS in the absence of "significant new information which questions the safety or effectiveness of the drug."

Finally, we turn to the district court's belief that it lacked, or should not have exercised, jurisdiction over the "new drug" and "grandfather clause" questions in this case. The court's declaration that "[i]t is not within the jurisdiction of this Court to determine whether the drug in issue is or is not a new drug" is plainly incorrect. Jurisdiction over the new drug issue is shared by the FDA, *see Weinberger* v. *Bentex Pharmaceuticals, Inc.*, 412 U.S. 645, 653 (1973); *Hynson, supra,* 412 U.S. at 624, and the federal district courts, *see CIBA Corp.* v. *Weinberger,* 412 U.S. 640, 644 (1973); *Premo Pharmaceutical, supra,* 629 F.2d at 801; *United States* v. *X-OTAG Plus Tablets",* 602 F.2d 1387 (10th Cir. 1979); *United States* v. *Mosinee Research Corp.,* 583 F.2d 930, 931-32 (7th Cir. 1978).

Further, the district court's invocation of the doctrine of "primary jurisdiction" to justify its refusal to exercise its own jurisdiction is not persuasive. As we have elsewhere stated, deference to an agency's primary jurisdiction makes little sense in the context of an enforcement proceeding initiated by the agency. *ICC* v. *B & T Transportation Co.*, 613 F.2d 1182, 1187 (1st Cir. 1980). This is especially true where, as here, a party remains subject to the agency's regulatory efforts despite the remand. We have held above that a district court lacks the power to require the FDA to defer seizures *pendente lite* or to order release of seized drugs prior to a determination of the merits of the agency's claims. The effect of a remand to the agency thus would hardly be beneficial to the product's manufacturer. Without the relief afforded by the other aspects of the district court's order, Alcon would be deprived of a judicial remedy in return for an administrative procedure of uncertain duration before an unsympathetic agency. We would be surprised if either Alcon or the district court would be content with a remand under such circumstances. With this consideration in mind, and in view of the fact that the FDA's current position on the "new drug" status of WANS is already clear; that the FDA carries the burden of proving its position at trial; and that the agency has no duty to hold a pre-enforcement hearing or to justify its action under its Compliance Policy Guide, *see supra,* we do not see what would be gained in this case by a remand. At least it can be said that two fundamental purposes of deference to agency jurisdiction — "coordinating administrative and judicial machinery" and assuring uniformity of regulation, *Mashpee Tribe* v. *New Seabury Corp.*, 592 F.2d 575, 580 (1st Cir.), *cert. denied,* 444 U.S. 866 (1979) — would not be served by the district court's order. *See generally Litton Systems, Inc.* v. *Southwestern Bell Telephone Co.*, 539 F.2d 418 (5th Cir. 1976); *Mississippi Power & Light Co.* v. *United Gas Pipe Line Co.*, 532 F.2d 412 (5th Cir. 1976), *cert. denied,* 429 U.S. 1094 (1977); *ICC* v. *All-American, Inc.*, 505 F.2d 1360, 1362-64 (7th Cir. 1974).

This is not to say that a remand in the context of enforcement proceedings might never be appropriate. In *Bentex Pharmaceuticals, supra,* 412 U.S. 645, the Supreme Court upheld the power of a district court to refer to the FDA "new drug" and "grandfather clause" issues initially presented to the court in a declaratory judgment action instituted by drug manufacturers. The Court went on to note that a court could stay its hand "[e]ven where no . . . administrative determination has been made and the issue arises in a district court in enforcement proceedings. . . ." 412 U.S. at 652. This observation, however, should be understood in relation to the situation in *Bentex,* where some 21 drug manufacturers had requested declaratory relief. There the court was in essence being asked to issue, without benefit of prior administrative proceedings, a decision upon whether a substantial portion of an industry was complying with the Act. Here the district court is being asked only to decide whether a single drug manufactured by a single company is being marketed illegally. The agency's view of the question is clear and will have to be substantiated for the agency to prevail in court. We therefore conclude that under *Bentex* this is not an appropriate case for a remand.

As the district court recognized, a third purpose of the doctrine of primary jurisdiction — taking advantage "of agencies' special expertise," *Mashpee Tribe, supra,* 592 F.2d at 580 — weighs in favor of a remand, but not, we think, decisively. The Supreme Court has described the "new drug" and "grandfather clause" issues as "the kinds of issues peculiarly suited to initial determination by the FDA." *Bentex Pharmaceuticals, supra,* 412 U.S. at 653. Nevertheless, contrary to the Court's suggestion it has not been "commonplace" for courts to await an appropriate administrative declaration in enforcement proceedings, *Bentex, supra,* 412 U.S. at 652; lower courts continue to hear and decide the "new drug" status of drugs challenged by the FDA in seizure and injunction actions. *See, e.g., Premo Pharmaceuticals, supra,* 629 F.2d at 804-05 (issue decided by the court of ap-

peals); *"X-OTAG Plus Tablets"*, *supra*, 602 F.2d 1387; *Mosinee Research*, *supra*, 583 F.2d 930; *United States* v. *Articles of Drug . . . Horomin* [*sic*], No. 80-587 (D.N.J. Aug. 29, 1980). The government asserts, and we have found nothing to the contrary, that of the hundreds of enforcement actions brought by the FDA under section 505 since 1938, none save the present has been remanded to the agency. Returning issues in an enforcement action to the FDA imposes an administrative burden for which the Act makes no provision, and insofar as the procedure delays adjudication of the regulatory status of a drug, may work to the disadvantage not only of the agency and public, but also of the manufacturer. In such circumstances the power to remand must be used sparingly. Had the trial set for May 1979 been held, WANS' status would long since have been laid to rest. In deciding the case, the FDA's expertise would have been available to the court, in that to sustain its burden the agency would have had to present expert evidence establishing its claims regarding WANS. We therefore conclude that the district court erred in remanding the case to the FDA.

The orders of the district court are vacated and the case is remanded for further proceedings consistent with this opinion.

APPENDIX B

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

Nos. 80-1188, 1357

(Entered February 24, 1981)

UNITED STATES OF AMERICA,

v.

ALCON LABORATORIES, ETC., *et al.*

JUDGMENT

This cause came on to be heard on appeal from the United States District Court for the District of Puerto Rico, and was argued by counsel.

Upon consideration whereof, It is now here ordered, adjudged and decreed as follows: The orders of the district court are vacated and the case is remanded for further proceedings consistent with the opinion filed this day.

Costs to appellant.

By the Court:

/s/ DANA H. GALLUP
Clerk

APPENDIX C

IN THE UNITED STATES DISTRICT COURT
FOR THE
DISTRICT OF PUERTO RICO

Nos. 78-2378, 78-1830, 80-243

(Filed February 27, 1980)

UNITED STATES OF AMERICA,

v.

ALCON LABORATORIES (PUERTO RICO), INC., ET AL.

Before Juan M. Perez Gimenez, *Judge*.

ORDER

Consolidated actions Civil 78-2378 and Civil 78-1830 came to be heard on motion of defendants for an order remanding this action to the Food and Drug Administration with instructions to defer regulatory enforcement action until or unless certain conditions are fulfilled.

In view that the seizure action which the Government filed on January 28, 1980, Civil 80-243, and accomplished on February 15, 1980, presents essentially the same issues as those in consolidated actions Civil 78-2378 and Civil 78-1830 the Court ORDERS

That Civil 80-243 be consolidated with prior consolidated actions No. 78-2378 and 78-1830.

After a careful examination of the arguments presented by the parties the Court FURTHER ORDERS

That this action be and it is hereby remanded to the Food and Drug Administration (FDA) with instructions to defer regulatory action against the WANS preparations involved in this matter or against defendants based upon the alleged "new drug" status of WANS until FDA holds a hearing pursuant to 5 USC § 554 and thereafter makes an administrative determination of the new drug status as WANS in conformity with the enforcement priorities enunciated in FDA's Compliance Policy Guide 7132c. 08.

Accordingly, it is FURTHER ORDERED

That prior seizures ordered by the Court are left without effect.

However, jurisdiction will be retained whether new, verifiable and genuinely significant information comes to light which questions the safety or efficacy of a WANS preparation so as to justify enforcement action against such preparation out of the sequence provided by the Agency's Compliance Policy Guide 7132c. 08.

Shortly hereafter, this Court will render an Opinion with a detailed analysis of the legal grounds for the instant REMAND.

IT IS SO ORDERED.

In San Juan, Puerto Rico, this 27th day of February, 1980.

/s/ JUAN M. PEREZ GIMENEZ
Juan M. Perez Gimenez
U.S. District Court Judge

APPENDIX D

IN THE UNITED STATES DISTRICT COURT
FOR THE
DISTRICT OF PUERTO RICO

Nos. 78-2378, 78-1830, 80-243

(Filed April 9, 1980)

UNITED STATES OF AMERICA,

v.

ALCON LABORATORIES (PUERTO RICO), INC., ET AL.

Before Juan M. Perez Gimenez, *Judge*

OPINION AND ORDER

Through an order issued by this Court on February 27, 1980, this matter was remanded to the Food and Drug Administration for further proceedings "with instructions to defer regulatory action against the WANS preparations involved in the matter against defendants, based upon the alleged 'new drug' status of WANS until F.D.A. holds a hearing pursuant to 5 U.S.C. 554, and thereafter makes an administrative determination of the new drug status as WANS in conformity with the enforcement priorities enunciated in F.D.A.'s Compliance Policy Guide 7132c.08".

The present matter consists of three consolidated actions presenting similar issues.[1] Involved herein are a series of peti-

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[1] Two of the three actions, Civil No. 78-1830 and 80-0243, are seizure actions. The other, Civil No. 78-2378, is an injunctive action, whereby the Food and Drug Administration sought to

tions for seizure and condemnation by the United States of America under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301, et seq., for seizure and condemnation of WANS, and any other article of drug consisting of pyrilamine maleate and pentobarbital sodium, manufactured by Alcon Laboratories (Puerto Rico), Inc., Humacao, Puerto Rico, alleging that the aforesaid articles are held illegally within the jurisdiction of the Court since they are new drugs which may not be introduced or delivered for introduction into interstate commerce.

The Government has alleged that the specific articles of drug are "new drugs" within the meaning of Section 201(p) of the Federal Food, Drug and Cosmetic Act (the Act), 21 U.S.C. 321(p), and that the articles are misbranded under Section 502(f)(1) of the Act, 21 U.S.C. 352(f)(1), in view that their labeling fails to bear adequate directions for use.

The term "new drug" is defined in 21 U.S.C. 321(p) as follows:

> "(1) Any drug . . . the composition of which is such that such drug is not generally recognized among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof. . . .
>
> "(2) Any drug . . . the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions has become so recognized, but which has not, otherwise, than in such investigations been used to a material extent or for a material time under such conditions."

On the other side, Alcon denies that the seized articles are "new drugs", and advances three additional arguments in support of its position, to wit: (1) that the drugs are entitled

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enjoin the defendants from introducing WANS into interstate commerce without an approved new drug application, a petition for temporary retraining [*sic*] order was denied on November 29, 1978.

to the protection under the 1962 "grandfather" clause; (2) that regulatory action is premature because there is no significant new information which questions the safety or effectiveness of the drugs within the meaning of the F.D.A.'s Compliance Policy Guide 7132c.08 (21 C.F.R. 10.85(e));[2] (3) that the initiation of enforcement actions against WANS based upon the marketing of WANS without an approved N.D.A. (New Drug Application) not only violates F.D.A.'s own rules, policies and regulations (21 C.F.R. 10.85(e)), but that it is also not in accordance with the law, 5 U.S.C. 706(2)(A).[3]

In the instant case the Government instituted these actions based on information obtained by the Food and Drug Administration which relates to reports of adverse reactions in

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[2] 21 C.F.R. 10.85(e), (f), provide: "(e) An advisory opinion represents the formal position of the Food and Drug Administration on the matter involved, and except as provided in paragraph (f) of this section obligates the agency to follow it until it is amended or revoked. The Commissioner shall not recommend legal action against any person or product with respect to any action taken in conformity with an advisory opinion which has not been amended or revoked.

"(f) In unusual situations involving an immediate and significant danger to health, the Commissioner may take appropriate civil enforcement action contrary to an advisory opinion issued pursuant to this section prior to amending or revoking such advisory opinion as provided in paragraph (g) of this section. Appropriate amendment or revocation of the advisory opinion involved shall be expedited."

[3] 5 U.S.C. 706(2)(A) provides: "To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions and determine the meaning or applicability of the terms of an agency action. The reviewing court shall:

(2) hold unlawful and set aside agency action, findings, and conclusions found to be

(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."

children who were treated for nausea and vomiting with drugs containing pyrilamine maleate and pertobarbital [*sic*] sodium.

Alcon contends that the information is not new information within the meaning of the Compliance Policy Guide. It is averred that the seven adverse reactions in question occurred between 1970 and 1974 (as per deposition of Dr. James F. Schwartz on February 13, 1979), that the attending physicians, contrary to what they say, did not consider these reactions significant enough at the time in view of the failure to report them to the Food and Drug Administration (as per Dr. Pruitts' deposition, p. 40), and that the regulatory letter was issued more than 14 months later from the period of time mentioned before.

The validity of the "new information" has been further challenged by Alcon. It has been alleged that each adverse reaction was associated with an "overdose" and that each patient was dehydrated; that dehydration itself produces similar symptoms.[4] Additionally, there is the fact that in most of the cases cited the patient was receiving or had recently received other drug therapy.

Furthermore, there are discrepancies between Dr. Pruitt's Drug Experience Reports as submitted to F.D.A. and Dr. Schwartz' notes from the hospital charts of the seven patients as to the amount, dosage, strength, and brand name of the antihistamine barbiturate drug administered, and as to the prior or concurrent drug therapy.

Certainly, in these actions complex technical determinations are involved concerning the "new drug" issue. The definition of "new drug" as used in Section 201(p), involves a determination of technical and scientific questions by experts. *Ciba Corp.* v. *Weinberger,* 412 U.S. 640 643 (1973).

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[4] Dr. Pruitt, who collected the information on the adverse reactions cited by F.D.A., indicated that lack of drug therapy in cases of pernicious vomiting can cause dehydration which in turn can result in the same adverse reactions said to be associated with the antihistamine barbiturate products.

Moreover, the determination of whether a drug is generally recognized as safe and effective within the meaning of Section 201(p)(1) necessarily implicates complex chemical and pharmacological considerations. *Weinberger* v. *Bentex Pharmaceuticals,* 412 U.S. 645 (1973). When as in the present action there are conflicts arising from the medical data, an order to remand would be the most adequate determination.

In the case of *Weinberger* v. *Bentex Pharmaceuticals, supra,* the United States Supreme Court ruled that the evaluation of conflicting reports as to the reputation of drugs among experts in the field is not a matter well left to a court without chemical or medical background, and further established that threshold questions within the peculiar expertise of an administrative agency are appropriately routed to the agency, while the courts stays its hand. *Weinberger. Bentex, supra,* at 653-654.

The present actions have been instituted without a formal administrative determination of the "new drug" status of WANS, the issue first being tendered to the district court.

The Act does not create a dual system of control, one administrative and one judicial, for it is the agency's primary jurisdiction to determine the status of drugs under the Act. Thus, issues presented herein may be more effectively evaluated at the administrative than at the judicial level, and a remand would promote both administrative and judicial economy. The question whether the drug is to be recognized as "safe and effective" or was "grandfathered in" are the kinds of issues peculiarly suited to initial determination by the Food and Drug Administration. *Weinberger* v. *Bentex, supra,* at 653.

Given the present state of the evidence on record, a remand would be the most proper action to be taken. *Weinberger* v. *Bentex, supra,* at 654.

It is not within the jurisdiction of this Court to determine whether the drug in issue is or is not a new drug. Such decision corresponds, and is to be made by the Food and Drug

Administration, the Agency entrusted by Congress with the necessary expertise to make a responsible determination. A remand to the F.D.A. would be the most appropriate action to be taken in view of the characteristics of the case as reflected through information generated by the discovery had so far in the cases and which appears on the record.

There is evidence in the record which establishes that the WANS proportions have been used under medical supervision for approximately twenty five years. In conjunction with this fact we have to consider that the alleged "new information" poses a series of conflicts when examined with other evicence on record. Both factors are determinant for any conclusion by the Court as to whether regulatory action against WANS violates C.P.G.[5]

Since no final determination has been made with respect to WANS, in order to proceed or initiate regulatory action against the product, there must be significant new information which questions the safety of the drug. At this stage, and in the light of the "new information" the Court cannot make a well-informed decision and is unable to determine the direct relationship establishing that WANS is an unsafe product. As a corollary to this, the Court, given the conflicts which appear from the evidence, is in no position to ascertain whether the F.D.A.'s enforcement actions against WANS are consistent with its Compliance Policy Guide.[6]

This Court finds that issues pending in these actions revolve and are dependent on the "new drug" status of the WANS, this in turn being a matter to be resolved at the agency level. *C.B.A. Corp.* v. *Weinberger, supra.*

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[5] The Food and Drug Administration's Compliance Policy Guide 7132c.08 constitutes an advisory opinion/guideline enunciating F.D.A.'s "new drug" enforcement properties. 21 C.F.R. 10.85, 10.90.

[6] It has been established that enforcement actions premised upon the Government's contravention of the Compliance Policy Guide cannot stand. *N.L.R.B.* v. *Welcome American Fertilizer Co.*, 443 F.2d 19 (9 Cir. 1971).

Wherefore, in view of the foregoing, the Court hereby ORDERS that consolidated cases Civil Nos 78-2378, 78-1830 and 80-0243, be remanded to the Food and Drug Administration to hold a formal administrative hearing pursuant to 5 U.S.C. 554 on the issue as to whether WANS is a "new drug" in conformity with the enforcement priorities enunciated in F.D.A.'s Compliance Policy Guide 7132c.08.

The Court will retain jurisdiction over these actions for purposes of (1) determining whether any verifiable and genuinely significant new information comes to light which questions the safety and efficacy of a WANS preparation so as to justify enforcement action against such preparations out of the sequence provided by the Agency's Compliance Policy Guide 7132c.08, and; (2) resolving any issues remaining following the issuance of a final administrative order after a formal administrative hearing on the "new drug" status of WANS in conformity with the enforcement priorities established in Compliance Policy Guid [*sic*] 7132c.08.

IT IS SO ORDERED.

San Juan, Puerto Rico, April 8, 1980.

/s/ JUAN M. PEREZ-GIMENEZ
Juan M. Perez-Gimenez
U. S. District Judge

APPENDIX E

IN THE UNITED STATES DISTRICT COURT
FOR THE
DISTRICT OF PUERTO RICO

Nos. 78-2378, 78-1830, 80-0243

(Filed April 29, 1980)

UNITED STATES OF AMERICA

v.

ALCON LABORATORIES (PUERTO RICO), INC., ET AL.

Before Juan M. Perez Gimenez, *Judge*

ORDER

On February 27, 1980, this Court entered an order remanding this matter to the Food and Drug Administration. The government was instructed to defer regulatory action against the products involved herein, and it was further ordered that the preceding seizure action be left without effect.

Thereafter the plaintiff moved for a stay of the order pending appeal. The motion, having been opposed by defendants and having been extensively argued by the parties, now stands submitted pending decision by this Court.

The government's motion is grounded on the contention that there is no statutory authority to enjoin the Food and Drug Administration from instituting seizure action under the Act. It strongly relies on the case of *Ewing* v. *Mytinger & Casselberry, Inc.*, 339 U.S. 594 (1950). However, the case is inapposite to the issues presented in the instant case. The issue

presented in *Ewing* v. *Mytinger, supra,* was whether the Food and Drug Administration should be enjoined from initiating enforcement action and not, as in the present case, whether after enforcement action has been initiated, the Court in the exercise of its sound discretion, can remand the case to the Agency for a formal administrative determination.

For the reasons advanced in our Opinion and Order of April 8, 1980, the matter was to be remanded to the Food and Drug Administration to determine whether the product is a "new drug".

Contrary to plaintiff's contention, even in enforcement proceedings, a remand may be ordered by the Court:

> "Even when no such administrative determination has been made and the issue arises in a district court in *enforcement proceedings,* it would be commonplace for the court to wait an appropriate administrative declaration before it acted." (Emphasis supplied) 412 U.S. 645, at 652 (1973).

In view of our findings to the effects that the product has been used for years, and considering the factors[1] which strengthen the Court's determination to remand, to allow the continued retention of the material seized would be an abuse of judicial discretion.

WHEREFORE, in view of foregoing, the government's motion for stay pending appeal is hereby DENIED; and it is further ordered that one box of each of WANS children, WANS #1, WANS #2, from each of the seizures, be retained under seal pending a final determination of the new drug status of WANS.

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[1] The information which prompted the F.D.A. to initiate these actions was not only contradictory, but also insufficient to allow a causal relation. In all but one case the reactions were associated with an overdos , and also there were alternative causes to which the adverse reactions may be attributed.

IT IS SO ORDERED.

San Juan, Puerto Rico, April 29, 1980.

/s/ JUAN M. PEREZ-GIMENEZ
Juan M. Perez-Gimenez
U. S. District Judge

APPENDIX F

1. 21 U.S.C. §334 provides in pertinent part:

(a) (1) Any article of food, drug, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce, or which may not, under the provisions of section 404 or 505, be introduced into interstate commerce, shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States or United States court of a Territory within the jurisdiction of which the article is found: *Provided, however,* That no libel for condemnation shall be instituted under this Act, for any alleged misbranding if there is pending in any court a libel for condemnation proceeding under this Act based upon the same alleged misbranding, and not more than one such proceeding shall be instituted if no such proceeding is so pending, except that such limitations shall not apply (A) when such misbranding has been the basis of a prior judgment in favor of the United States, in a criminal, injunction, or libel for condemnation proceeding under this Act, or (B) when the Secretary has probable cause to believe from facts found, without hearing, by him or any officer or employee of the Department that the misbranded article is dangerous to health, or that the labeling of the misbranded article is fraudulent, or would be in a material respect misleading to the injury or damage of the purchaser or consumer. In any case where the number of libel for condemnation proceedings is limited as above provided the proceeding pending or instituted shall, on application on the claimant, seasonably made, be removed for trial to any district agreed upon by stipulation between the parties, or, in case of failure to so stipulate within a reasonable time, the claimant may apply to the court of the district in which the seizure has been made, and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the

contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business to which the case shall be removed for trial.

* * *

(b) The article, equipment, or other thing proceeded against shall be liable to seizure by process pursuant to the libel, and the procedure in cases under this section shall conform, as nearly as may be, to the procedure in admiralty; except that on demand of either party any issue of fact joined in any such case shall be tried by jury. When libel for condemnation proceedings under this section, involving the same claimant and the same issues of adulteration or misbranding, are pending in two or more jurisdictions, such pending proceedings, upon application of the claimant seasonably made to the court of one such jurisdiction, shall be consolidated for trial by order of such court, and tried in (1) any district selected by the claimant where one of such proceedings is pending; or (2) a district agreed upon by stipulation between the parties. If no order for consolidation is so made within a reasonable time, the claimant may apply to the court of one such jurisdiction, and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, in which all such pending proceedings shall be consolidated for trial and tried. Such order of consolidation shall not apply so as to require the removal of any case the date for trial of which has been fixed. The court granting such order shall give prompt notification thereof to the other courts having jurisdiction of the cases covered thereby.

2. 21 U.S.C. §332 provides:

(a) The district courts of the United States and the United States courts of the Territories shall have jurisdiction, for cause shown, and subject to the provisions of section 381 (relating to notice to opposite party) of Title 28, to restrain violations of section 301 of this title, except paragraphs (h), (i), and (j) of said section.

(b) In case of violation of an injunction or restraining order issued under this section, which also constitutes a violation of this Act, trial shall be by the court, or, upon demand of the accused, by a jury. Such trial shall be conducted in accordance with the practice and procedure applicable in the case of proceedings subject to the provisions of section 22 of such Act of October 15, 1914, as amended. [This section, which appeared as U.S.C., title 28, sec. 387, has been repealed. It is now covered by Rule 42(b), Federal Rules of Criminal Procedure.]

3. 21 U.S.C. §321 provides in pertinent part:

For the purposes of this Act — (p) The term "new drug" means — (1) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to the enactment of this Act it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

(2) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

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* "ENACTMENT DATE" AS DEFINED IN DRUG AMENDMENTS ACT OF 1962

Sec. 107 of P.L. 87-781

Sec. 107(c)(1) [As used in this subsection] the term "enactment date" means the date of enactment of this Act; and the term "basic

4. 21 U.S.C. §355 provides in pertinent part:

(a) No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) is effective with respect to such drug.

Act" means the Federal Food, Drug, and Cosmetic Act.

(2) An application filed pursuant to section 505(b) of the basic Act which was "effective" within the meaning of that Act on the day immediately preceding the enactment date shall be deemed, as of the enactment date, to be an application "approved" by the Secretary within the meaning of the basic Act as amended by this Act.

(3) In the case of any drug with respect to which an application filed under section 505(b) of the basic Act is deemed to be an approved application on the enactment date by virtue of paragraph (2) of this subsection —

(A) the amendments made by this Act to section 201(p), and to subsections (b) and (d) of section 505, of the basic Act, insofar as such amendments relate to the effectiveness of drugs, shall not, so long as approval of such application is not withdrawn or suspended pursuant to section 505(e) of that Act, apply to such drug when intended solely for use under conditions prescribed, recommended, or suggested in labeling covered by such approved application, but shall apply to any changed use, or conditions of use, prescribed, recommended, or suggested in its labeling, including such conditions of use as are the subject of an amendment or supplement to such application pending on, or filed after, the enactment date; and

(B) clause (3) of the first sentence of section 505(e) of the basic Act, as amended by this Act, shall not apply to such drug when intended solely for use under conditions prescribed, recommended, or suggested in labeling covered by such approved application (except with respect to such use, or conditions of use, as are the subject of an amendment or supplement to such approved application, which amendment or supplement has been approved after the enactment date under section 505 of the basic Act as amended by this Act) until whichever of the following first occurs: (i) the expiration of the two-year period beginning with the enactment date; (ii) the effective date of an order under section 505(e) of the basic Act, other than clause (3) of the first sentence of such section 505(e), withdrawing or suspending the approval of such application.

5. 21 U.S.C. §351 provides in pertinent part: A drug or device shall be deemed to be adulterated—

(a)(1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or (2)(A) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this Act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess; or (3) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (4) if (A) it bears or contains, for purposes of coloring only, a color additive which is unsafe within the meaning of section 706(a), or (B) it is a color additive the intended use of which in or on drugs or devices is for purposes of coloring only and is unsafe within the meaning of section 706(a); or (5) if it is a new animal drug which is unsafe within the meaning of section 512; or (6) if it is an animal feed bearing or containing a new animal drug, and such animal feed is unsafe within the meaning of section 512.

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(4) In the case of any drug which, on the first day immediately preceding the enactment date, (A) was commercially used or sold in the United States, (B) was not a new drug as defined by section 201(p) of the basic Act as then in force, and (C) was not covered by an effective application under section 505 of that Act, the amendments to section 201(p) made by this Act shall not apply to such drug when intended solely for use under conditions prescribed, recommended, or suggested in labeling with respect to such drug on that day.]

6. 21 U.S.C. §352 provides in pertinent part:

A drug or device shall be deemed to be misbranded —

* * *

(j) If it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

FILED
APR 30 1981
ALEXANDER L. STEVAS
CLERK

No. 80-1607

In the Supreme Court of the United States

OCTOBER TERM, 1980

ALCON LABORATORIES (PUERTO RICO), INC., ET AL.,
PETITIONERS

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

WADE H. MCCREE, JR.
Solicitor General

WILLIAM F. BAXTER
Assistant Attorney General

ROBERT B. NICHOLSON
ANDREA LIMMER
Attorneys

Department of Justice
Washington, D.C. 20530
(202) 633-2217

JEFFREY B. SPRINGER
Acting Chief Counsel

FORREST T. PATTERSON
Associate Chief Counsel
for Enforcement
Food and Drug Administration
Rockville, Maryland 20857

QUESTIONS PRESENTED

1. Whether a district court may enjoin the government from bringing any seizure or injunction action with regard to the illegal marketing of an alleged unapproved "new drug" pending an agency hearing ordered by the court into the "new drug" status of the product.

2. Whether, in an action to seize illegally marketed "new drugs," the district court erred in remanding the new drug issue to the FDA.

3. Whether 28 U.S.C. 2105 barred the court of appeals from reviewing the orders of the district court enjoining agency enforcement, dissolving the seizure of misbranded drugs, and remanding the "new drug" issues to the FDA.

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In the Supreme Court of the United States

OCTOBER TERM, 1980

No. 80-1607

ALCON LABORATORIES (PUERTO RICO), INC., ET AL.,
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v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-23a) is not yet reported. The opinion and order of the district court (Pet. App. 27a-33a) is not reported.

JURISDICTION

The judgment of the court of appeals (Pet. App. 24a) was entered on February 24, 1981. The petition for a writ of certiorari was filed on March 23, 1981. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. Alcon Laboratories makes drug suppositories called WANS No. 1, WANS No. 2, and WANS Children Anti Nausea Supprettes ("WANS"), which it sells for use in the symptomatic treatment of nausea and vomiting. The drugs' active ingredients are pyrilamine maleate (an antihistamine) and pentobarbital sodium (a barbiturate). The Food and Drug Administration ("FDA") has never approved the marketing of these ingredients or any similar combination drug for the treatment of nausea and vomiting (Pet. App. 1a-2a).

On March 17, 1978, FDA informed Alcon and other drug companies that the agency's Neurological Drugs Advisory Committee had reported that children treated for nausea with drugs containing pyrilamine maleate and pentobarbital had experienced severe and sometimes fatal reactions.[1] The agency further stated that there is no evidence of the safety and efficacy of pyrilamine maleate with or without a barbiturate in the treatment of nausea and vomiting. It advised Alcon and all other known manufacturers of fixed-combination pyrilamine maleate pentobarbital sodium antiemetic suppositories that these drugs are unapproved new drugs[2] being marketed in violation

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[1] Although petitioners have argued that FDA did not in fact have reports of fatal reactions, they do not dispute that there are reports of severe reactions to the drugs.

[2] Section 201(p) of the Federal Food, Drug, and Cosmetic Act defines a "new drug" as a drug not generally recognized by qualified experts as safe and effective for its intended use. 21 U.S.C. 321(p). It is illegal to market a new drug unless the FDA has approved a new drug application ("NDA") for it. See Section 505 of the Act, 21 U.S.C. 355; *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609 (1973).

of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 *et seq.*, and that, unless they stopped manufacturing the drugs, FDA would initiate legal action under the seizure and/or injunction provisions of the Act. All manufacturers except Alcon acceded to the FDA's request to cease the manufacture and interstate distribution of these drugs (Pet. App. 3a-4a).

On April 3, 1978, Alcon responded that while FDA had never approved the drug, WANS needed no regulatory approval because it was generally recognized as safe and effective by experts and thus was not a "new drug" within the meaning of Section 201(p) of the Act, 21 U.S.C. 321(p). Alcon submitted to the FDA published and unpublished reports purporting to establish the safety and efficacy of WANS. Although Alcon refused to discontinue marketing WANS, it suggested that it would relabel the product in light of an FDA Report that WANS may be unsafe when administered to children under the conditions of use recommended in WANS labeling. After reviewing these submissions, the FDA concluded that Alcon had not produced satisfactory evidence to support the safety and efficacy of WANS, and that WANS could not be brought into compliance with the Act merely by relabeling the product (Pet. App. 4a-5a).

2. On September 21, 1978, the United States filed a complaint for forfeiture in the United States District Court for the District of Puerto Rico against all lots of WANS products in petitioners' possession. The complaint alleged that the products are misbranded within the meaning of Section 502(f)(1) of the Act, 21 U.S.C. 352(f)(1), since they are "new drugs" which have not been approved for marketing. Shortly thereafter, the United States Marshal seized approximately 454,000 WANS suppositories. Peti-

tioners admitted that the drugs did not have regulatory approval but argued that no such approval was necessary because the drugs are not "new drugs" within the meaning of the Act. Because petitioners continued to make and distribute WANS, two months later the United States sought an injunction barring petitioners from distributing WANS until the FDA issues an approved new drug application covering that drug.[3] The district court denied a request for a temporary restraining order and deferred ruling on the requests for a preliminary and permanent injunction (Pet. App. 5a).

The district court consolidated the seizure and injunction actions, gave the parties 90 days to complete discovery, and set trial for May 7, 1979 (Pet. App. 5a). On March 21, 1979, however, petitioners moved to continue the trial date, and to remand the case to the FDA "with instructions to defer regulatory action against * * * WANS * * * or against defendants based upon the alleged 'new drug' status of WANS until FDA makes an administrative determination of the new drug status of WANS in conformity with the enforcement priorities enunciated in FDA's Compliance Policy Guide 7132c.08" (Pet. App. 6a). On April 19, 1979, the court rescinded the scheduled trial date without setting a new date. The government opposed the motion for remand and promptly asked the court to reinstate the trial date or to schedule a prompt hearing on its request for a preliminary injunction. More than eight months later, while the government's motions were

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[3] Section 301(d) and (*l*) prohibits the introduction into interstate commerce of unapproved new drugs, or the doing of any act which results in the misbranding of a drug held for sale after shipment in interstate commerce. 21 U.S.C. 331(d) and (*l*). Section 302 authorizes injunctive actions to prevent violations of Section 301. 21 U.S.C. 332.

still pending, the United States filed a second seizure action against WANS in the district court.

3. On February 27, 1980, the court issued, without opinion, an order (1) consolidating the two seizure actions and the injunction action; (2) remanding the proceedings to the FDA to hold a hearing pursuant to 5 U.S.C. 554 on the "new drug" status of WANS; (3) enjoining FDA from taking enforcement action against WANS or petitioners pending "an administrative determination of the new drug status [of] WANS in conformity with the enforcement priorities enunciated in FDA's Compliance Policy Guide 7132c.08," and (4) rendering the prior seizures "without effect" (Pet. App. 25a-26a).

On April 9, 1980, the district court issued an opinion and order to accompany the order of February 27 (Pet. App. 27a-33a). Addressing only the decision to remand the new drug issue to FDA (*id.* at 31a-32a), the court held that the evidence concerning WANS' new drug status was not conclusive, and that this complex and technical question should be remanded to FDA for its initial determination (*id.* at 30a-31a). The district court did not explain why it dissolved the seizures, failed to act on the government's request for an injunction, or enjoined further FDA enforcement.

4. On the government's appeal of both the February and April orders, the court of appeals consolidated the appeals, vacated the district court's orders, and remanded the case for trial (Pet. App. 1a-23a). Relying on *Ewing* v. *Mytinger & Casselberry, Inc.*, 339 U.S. 594 (1950), the court of appeals determined that the district court was without authority to enjoin the government from filing seizure or injunctive actions against WANS and petitioners (Pet. App. 7a-9a).

In addition, the court of appeals ruled that the district court had improperly dissolved the WANS seizures without first determining the "new drug" issue (*id.* at 10a-12a). The court of appeals further concluded that the FDA had not violated its internal enforcement guidelines by seeking enforcement in this case before holding a formal administrative hearing on the new drug issue (*id.* at 17a-20a). Finally, the court of appeals held that the district court had jurisdiction to make a "new drug" determination, and that the doctrine of primary jurisdiction was inapplicable here because the agency itself had initiated enforcement proceedings in the district court in accordance with the Act and because a remand to the agency would only delay the adjudication of the "new drug" status of WANS (*id.* at 17a-23a).[4]

ARGUMENT

The court of appeals' decision is correct and is consistent with the uniform decisions of this Court and of the courts of appeals. Further review of this interlocutory decision is plainly unwarranted.

1. The court of appeals correctly held that the district court lacked authority to enjoin the government from filing seizure or other enforcement actions against WANS pending a court-ordered remand to the FDA. As this Court explained in *Ewing* v. *Mytinger & Casselberry, Inc.*, 339 U.S. 594, 601 (1950),

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[4] The court also found (Pet. App. 8a, 10a, 12a-14a) that the government could appeal the district court's preliminary injunction under 28 U.S.C. 1292(a)(1), and could appeal the district court's order dissolving the seizures and remanding the case to the agency under the collateral order doctrine. See *Cohen* v. *Beneficial Industrial Loan Corp.*, 337 U.S. 541 (1949); *Swift & Co. Packers* v. *Compania Colombiana Del Caribe*, 339 U.S. 684 (1950).

a district court cannot "step in, stay the institution of seizures, and bring the administrative regulation to a halt until it hears the case." The *Ewing* decision, which is the cornerstone of public health protection, reflects congressional intent to permit the FDA to initiate seizure and injunctive actions pending prompt judicial review of the dispute, thereby keeping potentially dangerous or ineffective drugs out of the public's hands. And this Court and the courts of appeals have repeatedly and uniformly endorsed the prophylactic *Ewing* rule. See, *e.g.*, *Calero-Toledo* v. *Pearson Yacht Leasing Co.*, 416 U.S. 663, 679 (1974); *Fuentes* v. *Shevin*, 407 U.S. 67, 92 & n.27 (1972); *Abbott Laboratories* v. *Gardner*, 387 U.S. 136, 147-148 (1967); *Premo Pharmaceutical Laboratories, Inc.* v. *United States*, 629 F.2d 795, 301 (2d Cir. 1980); *Southeastern Minerals, Inc.* v. *Harris*, 622 F.2d 758, 763-765 (5th Cir. 1980); *Pharmadyne Laboratories, Inc.* v. *Kennedy*, 596 F.2d 568, 569-571 (3d Cir. 1979); *Parke, Davis & Co.* v. *Califano*, 564 F.2d 1200 (6th Cir. 1977), cert. denied, 435 U.S. 942 (1978); *Natick Paperboard Corp.* v. *Weinberger*, 498 F.2d 125, 127 (1st Cir. 1974).

Without citing any authority, petitioners erroneously suggest (Pet. 18-19 & n.14) that *Ewing* is applicable solely to seizure cases involving misbranded drugs, and is not controlling with regard to the seizure of "new drugs."[5] But the seizure of WANS

[5] Petitioners also contend (Pet. 19-20) that *Ewing* is distinguishable because the seizure actions in this case violated FDA's own internal guidelines, and are "without factual or legal justification." But the district court enjoined enforcement proceedings without first addressing those "factual or legal" issues. Nor did the district court find that the FDA had violated its regulations or otherwise acted in an improper manner. To the contrary, the court of appeals properly deter-

was based on charges of misbranding, since an unapproved new drug is a misbranded drug. Moreover, *Ewing* involved the same statutory provision that authorizes the seizures challenged here (21 U.S.C. 334) and that decision unquestionably governs the "regular operation of the seizure procedures established by the Act" (*Abbott Laboratories* v. *Gardner*, *supra*, 387 U.S. at 148), including the "new drug" seizure in this case. Accord, *Premo Pharmaceutical Laboratories, Inc.* v. *United States*, *supra* (new drug seizures); *Southeastern Minerals, Inc.* v. *Harris*, *supra* (seizure of unapproved new animal feed); *Pharmadyne Laboratories, Inc.* v. *Kennedy*, *supra* (new drug seizures); *Parke, Davis & Co.* v. *Califano*, *supra* (new drug seizures); *Natick Paperboard Corp.* v. *Weinberger*, *supra* (adulterated food). Petitioners' narrow construction of the *Ewing* doctrine would breach the broad public protection established by Congress and repeatedly enforced by the courts.[6]

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mined that the guidelines cited by petitioners are simply inapplicable to WANS (Pet. App. 17a-20a). We further note that the *Ewing* rule is controlling even where the FDA has improperly instituted an enforcement action. In *Ewing* itself, for example, the trial court had found that the multiple seizures were purposefully designed to harass the drug manufacturer and were an abuse of discretion (339 U.S. at 604 (Jackson, J., dissenting)). See also *Pharmadyne Laboratories, Inc.* v. *Kennedy*, *supra*, 596 F.2d at 571 n.6.

[6] Likewise, it is irrelevant that the district court enjoined only seizures "based upon a 'new drug' charge," while permitting FDA to seize WANS if it could show that the drug is " 'unsafe' or 'dangerous to health' " (Pet. 19 & n.15). In *Ewing*, the Court assumed that the drug was "not dangerous to health" and "relatively innocuous" (339 U.S. at 601). The Court nonetheless held that "the statutory scheme treats every 'misbranded article' the same in this respect" and it empha-

Petitioners' reliance (Pet. 20-21) on *Weinberger* v. *Bentex Pharmaceuticals, Inc.*, 412 U.S. 645 (1973), is misplaced. The *Bentex* opinion does not refer to the *Ewing* decision, which has subsequently been cited by this Court with approval (*Calero-Toledo* v. *Pearson Yacht Leasing Co.*, *supra*, 416 U.S. at 679), much less purport to overrule or restrict the *Ewing* doctrine. Rather, *Bentex* concerned a suit by several drug manufacturers for a declaratory judgment regarding the status of their drug. *At the FDA's request*, the district court remanded the case to the agency to allow it to make the "new drug" determination in the first instance. With the FDA's acquiescence, the district court enjoined all enforcement actions against the drug manufacturers in the interim. See *Bentex Pharmaceuticals, Inc.* v. *Richardson*, 463 F.2d 363, 369 (4th Cir. 1972). Thus, the only question before the Court in *Bentex* was whether the district court had authority in a declaratory judgment action to remand the new drug issue to the FDA at its request. In upholding the FDA's right to exercise primary jurisdiction in the circumstances of that case, the Court did not suggest that the district court may enjoin and remand an FDA enforcement action over the agency's objection.[7]

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sized that its decision "determines the jurisdiction of the District Court in all the cases in that category" (*ibid.*).

[7] *Rutherford* v. *United States*, 542 F.2d 1137 (10th Cir. 1976), is also readily distinguishable. In that unique case, a terminally-ill cancer patient sought a declaration that laetrile is not a new drug and an injunction precluding the agency from interfering with his personal supply of laetrile pending a determination of the drug's status by the agency. See *id.* at 1144 (McWilliams, J., dissenting). The court of appeals did not enjoin FDA enforcement actions against the drug distributors or against the drug generally. Furthermore, the

2. For similar reasons, the court of appeals correctly held (Pet. App. 21a) that the district court had improperly invoked the doctrine of primary jurisdiction in this case. At the outset, we note that a remand would be purposeless for petitioners unless it is coupled with an injunction against interim agency enforcement. Indeed, petitioners acknowledged in the court of appeals that "[a] remand in the absence of administrative restraint is simply meaningless" (Motion for Reconsideration, at 4). Because *Ewing* precludes the courts from enjoining or interfering with agency enforcement actions, a remand order would simply waste both petitioners' and the FDA's time and resources. In short, the court of appeals cannot be faulted for declining to uphold that portion of the district court's order that does not serve petitioners' ends.

At all events, petitioners' primary jurisdiction argument is wholly without merit. Since 1938 the government has brought hundreds of enforcement actions under Section 505 against unapproved new drugs. With the exception of the district court's order in this case, we are aware of no district court decision remanding an enforcement action to the agency for a new drug determination. In fact, in those few cases where defendants have sought to have the issue referred to the agency, the courts have uniformly refused to apply the primary jurisdiction doctrine. See, *e.g.*, *United States* v. *X-Otag Plus Tablets*, 602 F.2d

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Tenth Circuit has subsequently limited the *Rutherford* decision to its facts and reaffirmed that the district court should not remand a case to the agency where, as here, the FDA has initiated an enforcement action in district court. *United States* v. *X-Otag Plus Tablets*, 602 F.2d 1387, 1390-1391 (10th Cir. 1979).

1387 (10th Cir. 1979); *United States* v. *Mosinee Research Corp.*, 583 F.2d 930 (7th Cir. 1978). As the Second Circuit has explained, "when the agency chooses to go to the district court for enforcement, it makes little sense to refer the very question at issue to the agency." *CAB* v. *Aeromatic Travel Corp.*, 489 F.2d 251, 254 (1974). See also *ICC* v. *B&T Transportation Co.*, 613 F.2d 1182, 1187 (1st Cir. 1980); *Mississippi Power & Light Co.* v. *United Gas Pipe Line Co.*, 532 F.2d 412 (5th Cir. 1976), cert. denied, 429 U.S. 1094 (1977); *ICC* v. *All-American, Inc.*, 505 F.2d 1360, 1362 (7th Cir. 1974). Indeed, the deference for agency expertise and discretion in enforcement tactics that underlies both *Bentex* and *CIBA Corp.* v. *Weinberger*, 412 U.S. 640 (1973) (as well as *Ewing*) strongly supports the conclusion of the court of appeals in this case: where, as here, the agency believes that a drug is misbranded and may be unsafe or ineffective, Congress provided that the FDA could seek enforcement and determination of the new drug issue in district court.

3. Petitioners also erroneously claim (Pet. 23-26) that 28 U.S.C. 2105 barred court of appeals review in this case. That statute, which has generally been ignored or construed narrowly (see, *e.g.*, C. Wright, A. Miller & E. Cooper, *Federal Practice and Procedure* § 3903, at 414-415 (1976); *McGough* v. *First Arlington National Bank*, 519 F.2d 552, 554 (7th Cir. 1975)), applies only to "matters in abatement which do not involve jurisdiction." 28 U.S.C. 2105. Both the *Ewing* doctrine and the concept of primary jurisdiction involve jurisdictional matters, however (see 339 U.S. at 601; *Southeastern Minerals, Inc.* v. *Harris*, *supra*, 622 F.2d at 764 n.10), and thus do not fall

within the limited scope of Section 2105. See *Snyder* v. *Buck*, 340 U.S. 15, 22 (1950); C. Wright, A. Miller & E. Cooper, *supra*, at 413-414. See also *Weinberger* v. *Bentex Pharmaceuticals, Inc.*, *supra*; *Nader* v. *Allegheny Airlines, Inc.*, 426 U.S. 290 (1976) (involving appellate review of orders remanding a case to an agency under primary jurisdiction rationale). In addition, the district court retained jurisdiction over this case pending remand and therefore did not abate the case. See C. Wright, A. Miller & E. Cooper, *supra*, at 414.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

WADE H. MCCREE, JR.
Solicitor General

WILLIAM F. BAXTER
Assistant Attorney General

ROBERT B. NICHOLSON
ANDREA LIMMER
Attorneys

JEFFREY B. SPRINGER
Acting Chief Counsel

FORREST T. PATTERSON
Associate Chief Counsel
for Enforcement
Food and Drug Administration

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